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#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 1200 Pennsylvania Avenue NW

Washington, DC 20460

EPA Reg.	Number:
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Date of Issuance:

524-528

Term of Issuance:

Conditional

Name of Pesticide Product:

Corn Event MON863

NOTICE OF PESTICIDE:

X Registration Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you implement the following terms and conditions.

- 1) The subject registration will automatically expire on midnight May 1, 2004. The registration must expire on this date because this is the date of expiration of the tolerance exemption under 40 CFR 180.1214. When and if the Agency registers this product, it is our understanding that Monsanto intends to submit in the near future an amendment application to modify the expiration date and a petition to amend the tolerance exemption under 40 CFR 180.1214 so that its expiration date is removed. Based on the Agency's review of the data submitted and cited in support of this application, and provided that the Agency finalizes a rule which amends 40 CFR 180.1214 so that its expiration date is removed; the Agency anticipates at this time that an expiration date three years from the initial date of registration for this product would be appropriate.
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- 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

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- 5) Submit independent laboratory method validation (under OPPTS Guidelines 860.1340) to complete the database for Cry3Bb1 corn within 12 months of the date of registration. Provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a Cry3Bb1 analytical method within 6 months of the date of registration. The extraction and detection method as described for Cry3Bb1 protein appears to be adequate for analysis of Cry3Bb1 protein in corn grain. However, this method must be validated by both an independent laboratory and the EPA Biological and Economic Analysis Division laboratory before it can be considered a valid method. In addition, to assure that grain handlers have a test method in place prior to harvest, you must make available Cry3Bb1 strip tests to grain handlers and demonstrate to the Agency this provision prior to September 2003. EPA understands that these are 'qualitative' test kits and that you are in discussions with USDA/GIPSA about providing methodology and reagents for their use in developing a validated 'quantitative' method for MON 863 and that this transfer of materials will take place once registration occurs.
- 6) Submit expression data in terms of dry weight, as the amount of protein present in the given tissue. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data obtained for roots should also include typical times when corn rootworm would be feeding. Data are due within 24 months of the date of registration, provided the registration is amended to extend the registration date.
- 7) Submit field degradation studies evaluating accumulation and persistence of Cry3Bb1 in several different soils in various strata. Representative fields must have been planted with MON863 and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if Cry3Bb1 is accumulating or persisting in soil samples. A protocol is due within 90 days of the date of registration, and a progress report is due within one year of the date of registration. If the registration and tolerance exemption are amended to extend the expiration dates, a final report is due two years from the date of registration.
- 8) Submit laboratory toxicity tests with *Orius insidiosus* (minute pirate bug), carabid (ground beetle), and *Tetraopes* (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.
- 9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (the carabid and nematode data are of particular interest) and annual reports each year of this registration every April 30th.
- 10) Submit a six week broiler dietary study with 60% 70% MON 863 com in the diet that is of appropriate duration to represent the start and growing periods of the test species. Balanced diets should be formulated according to the National Research Council guidelines ("Nutrient Requirements of

Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.

- 11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.
  - Research regarding adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
  - Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
  - Research regarding the mechanism of potential resistance of CRW to MON 863 is necessary to
    develop an appropriate long-term IRM strategy. Monsanto must attempt to develop resistant CRW
    colonies to aid in determining selection intensity.
  - Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
  - Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤0.01.
  - Baseline susceptibility studies currently underway should be continued for WCRW and initiated
    for NCRW and monitoring techniques such as discriminating dose concentration assays need to be
    thoroughly investigated for their feasibility as resistance monitoring tools.
- 12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 com on a wide scale. (Note that this is not a required term or condition of the registration.)
- 13) You must implement the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 Bt corn has the following elements:

- 1] Requirements relating to creation of a non-Cry3Bb1 Bt com refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 Bt com;
- 2] Requirements for the registrants to prepare and require Crv3Bb1 Bt corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

- 4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the CAP already approved for MON810, EPA Registration Number 524-489);
- 5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;
- 6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Submit annual reports on sales(by state and county), IRM grower agreements results, compliance, and educational program on or before January 31st each year beginning in 2004.

# a. Refuge Requirements

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-Cry3Bb1 Bt corn that may be
  treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to
  apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are
  present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 consecutive rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will
  specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are
  present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

## b. Grower Agreements

- 1] Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] The registrant must develop a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm

annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.

- 4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- 5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.
- 6] The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* MON863 com seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

# c. IRM Education and IRM Compliance Monitoring Programs

- 1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON863 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON863 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON863 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- 2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3] Beginning January 31, 2004 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for

their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).

- 4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 Bt com product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON863 Bt com product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the CAP already approved for MON810, EPA Registration Number 524-489. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5] 15] below.
- 5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON863 Bt com.
- 6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
- 7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9] The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- 10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes to a previously approved CAP.

- 11] The registrant shall train its representatives who make on-farm visits with MON863 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- 13] If a grower, who purchases MON863 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- 14] Beginning January 31, 2004 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- 15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

# d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

- 1) The registrants will monitor for resistance and/or trends in increased tolerance for com rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. You must submit a protocol within 90 days of the date of registration.
- 2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.
- 3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.
- 5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30<sup>th</sup> each year for the duration of the conditional registration.

# e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm must be submitted by 1/31/2004. If resistance is confirmed, all MON863 acres (MON863 Bt fields and non-MON863 Bt refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

# **Annual Reports:**

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales Reported by county and state summed by state		January 31st each year beginning in 2004
Grower Agreement	Grower Agreement  Number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	
Grower Education	Education program completed previous year and plan for next year	January 31st each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31st each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15th each year and full report January 31st each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004

Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration		
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration		
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.		
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 <sup>th</sup> each year		

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Vanet L. Andersen, Ph.D, Director

Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

## Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: YieldGard® Rootworm: Rootworm Protection]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

## **Active Ingredient:**

## Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (ZMIR13L) in event MON 863 com...........0.00002 – 0.00003%

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

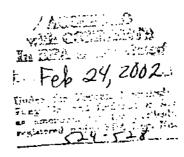
## **CAUTION**

® YieldGard is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017



## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

## **Insect Resistance Management**

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

## Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western com rootworm (Diabrotica virgifera virgifera) Northern com rootworm (Diabrotica barberi) Mexican com rootworm (Diabrotica virgifera zeae)



#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 1200 Pennsylvania Avenue NW Washington, DC 20460

EPA Reg. Number:

Date of Issuance:

524-528

Term of Issuance: NOTICE OF PESTICIDE:

X Registration

\_\_\_ Reregistration

(under FIFRA, as amended)

Conditional

Name of Pesticide Product:

Corn Event MON863

Name and Address of Registrant (include ZIP Code):

Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017

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EPA Form 1320-1A (1/90)

Printed on Recycled Paper

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- 7) Submit field degradation studies evaluating accumulation and persistence of Cry3Bb1 in several different soils in various strata. Representative fields must have been planted with MON863 and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if Cry3Bb1 is accumulating or persisting in soil samples. A protocol is due within 90 days of the date of registration, and a progress report is due within one year of the date of registration. If the registration and tolerance exemption are amended to extend the expiration dates, a final report is due two years from the date of registration.
- 8) Submit laboratory toxicity tests with Orius insidiosus (minute pirate bug), carabid (ground beetle), and Tetraopes (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.
- 9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (the carabid and nematode data are of particular interest) and annual reports each year of this registration every April 30th.

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appropriate duration to represer	at the area and CONCURRENCE	sere de la Calada	D	1 1 1 1 1 1 1	-1 - 1.1
10) Submit a six week broiler	dietary study with 60% -	<u>70%</u> MON 86	3 com in the	diet that is of	

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Poultry," Ninth Revised Edition, \$1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.

- 11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.
  - Research regarding adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
  - Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
  - Research regarding the mechanism of potential resistance of CRW to MON 863 is necessary to
    develop an appropriate long-term IRM strategy. Monsanto must attempt to develop resistant CRW
    colonies to aid in determining selection intensity.
  - Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
  - Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤0.01.
  - Baseline susceptibility studies currently underway should be continued for WCRW and initiated
    for NCRW and monitoring techniques such as discriminating dose concentration assays need to be
    thoroughly investigated for their feasibility as resistance monitoring tools.
- 12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 corn on a wide scale. [Note that this is not a required term or condition of the registration.]
- 13) You must implement the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 Bt com has the following elements:

- 1] Requirements relating to creation of a non-Cry3Bb1 Bt corn refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 Bt corn;
- 2] Requirements for the registrants to prepare and require Cry3Bb1 Bt corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;

3] Requirements	for the registrants to dev	velon <sup>c</sup> awayanawa	and report t	o EPA on pro	grams to educ	cate
SYMBOI growers about II	M requirements;			,		
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- 4] Requirements for the Tensis AJ fie venyi, completely, and report to EFF of programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the CAP already approved for MON810, EPA Registration Number 524-489);
- 5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;
- 6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Submit annual reports on sales(by state and county), IRM grower agreements results, compliance, and educational program on or before January 31st each year beginning in 2004.

## a. Refuge Requirements

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-Cry3Bb1 Bt corn that may be
  treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to
  apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are
  present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 consecutive rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will
  specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are
  present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

#### b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] The registrant	must develor	a system (eq	ui conguestu	ra is already	approved for	MON 810, EF	A Reg
SYMBO'N 524-489) wh	ich is reasona	bly likely to a	ssure that per	sons purchasi	ng the <i>Bt</i> con	n product will	affirm
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annually that they are contractually both to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.

- 4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- 5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.
- 6) The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON863 com seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

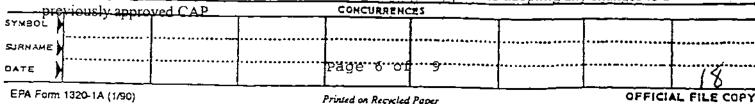
# c. IRM Education and IRM Compliance Monitoring Programs

- 1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON863 com users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON863 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON863 com user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- 2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Beginning Jan	mary 31, 2004	and annually	HGGWGWRAE WG	#registrants r	nust provide:	a report to EP	A
SYMBO'Summarizing the	activities carr	ied out under	the education	program for	the prior year	and the plans	for
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their education program dulling the current year. The registrand The SEDMIt a separate report or contribute to the report from the industry working group (ABSTC).

- 4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON863 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the CAP already approved for MON810, EPA Registration Number 524-489. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5] 15] below.
- 5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON863 Bt corn.
- 6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
- 7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9] The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- 10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes to a

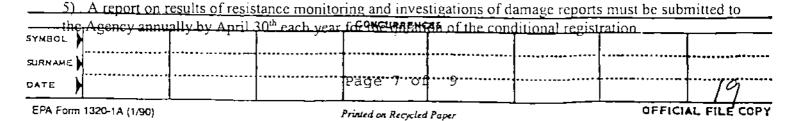


- 11] The registrant shall train its representances who make on the Partition with MON863 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- 13] If a grower, who purchases MON863 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- 14] Beginning January 31, 2004 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- 15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

# d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

- 1) The registrants will monitor for resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. You must submit a protocol within 90 days of the date of registration.
- 2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.
- 3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.



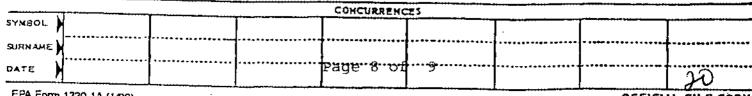
# e. Remedial Action Plans STATES ENVIRONMENTAL PROTECTION AGENCY

A Remedial Action Plan covering both suspected and confirmed resistance for com rootworm must be submitted by 1/31/2004. If resistance is confirmed, all MON863 acres (MON863 Bt fields and non-MON863 Bt refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

## **Annual Reports:**

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales Reported by county and state summed by state		January 31st each year beginning in 2004
Grower Agreement  Number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements		January 31st each year beginning in 2004
Grower Education	Education program completed previous year and plan for next year	January 31 <sup>st</sup> each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31st each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15th each year and full report January 31st each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004



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Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 <sup>th</sup> each year

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Janet L. Andersen, Ph.D. Director
Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

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#### MEMORANDUM

Consideration of Section 3(c)(7)(C) Conditional Registrations for the Monsanto SUBJECT:

Company Bt Corn Plant-Incorporated Protectant Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L)

in Event MON863 Corn: (EPA File Symbol 524-LEI)

-DECISION MEMORANDUM-

Biopesticides and Pollution Prevention Division FROM:

TO: James J. Jones, Deputy Director

Office of Pesticide Programs

#### I. ISSUE

Should the Agency conditionally register Monsanto Company's Bt com product pursuant to FIFRA  $\S3(c)(7)(C)$ ?

#### II. BACKGROUND

#### Active Ingredient

Cry3Bb1 protein is a delta-endotoxin from Bacillus thuringiensis spp. kumamotoensis and has activity against certain beetles. The wild-type cry3Bb1 gene was modified to enhance the protein's activity against the com root worm complex.

#### EUPs and Tolerance Exemption

Several experimental use permits and amendment/extensions have been granted by the Agency since April 2000 for different Cry3Bb1 com plant-incorporated protectants, EPA EUP Numbers 524-EUP-90, -92, and -93. A tolerance exemption was established for Bacillus thuringiensis Cry3Bb1 protein and the genetic material for its production in corn on May 11, 2001. This



tolerance exemption was codified under 40 CFR Part 180.1214 and expires on May 1, 2004. Monsanto has indicated their intent to submit a petition amending the Cry3Bb1 corn tolerance exemption to remove the expiration date once they obtain commercial approval.

## Registration Application and Public Comments

On March 1, 2001, EPA announced receipt of Monsanto's Event MON863 Cry3Bb1 com seed increase registration application (EPA File Symbol 524-LEI) pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (66 FR 15435). On March 13, 2002, EPA announced receipt of a revised application from Monsanto for EPA File Symbol 524-LEI for full commercial use. Finally, on July 24, 2002, EPA announced a meeting of the FIFRA Scientific Advisory Panel (SAP) to consider and review corn rootworm plant-incorporated protectant insect resistance management and non-target insect issues (67 FR 48461).

Approximately 937 comments were received by EPA in response to these announcements. Comments were received from private citizens, independent farmers, farm cooperatives, farm industry representatives, trade organizations, advocacy groups, academic researchers, and government officials. Comments received included handwritten letters, typed letters, e-mails, faxes, and slide presentations from the SAP meeting.

Several organizations interested in the registration of MON 863 sponsored letter writing campaigns to promote their interests and provided form letters for members or other interested citizens to submit to EPA. Six master form letters were identified. The originating organizations for these campaign letters were not apparent, and the master letters were identified on the basis of the most consistently copied text. Most of the 937 comments received were form letters (81 percent). In some cases the form letters were signed and mailed without alteration. However, many commenters added personalized comments or edited the form letters to better express their individual views.

About 88 percent of the 937 comments were received from private citizens. Support or opposition of the registration was not tracked for individual commenters; however, all six of the master form letters expressed support for the registration of MON 863. Based on the large number of form letters received and the large number of letters received from private citizens, most of the private citizens who commented on the application generally support registration.

Some of the major environmental or public interest groups included the Center for Science in Public Interest, Foundation E.A.R.T.H., Greenpeace, The Sierra Club, The Xerces Society, and Union of Concerned Scientists. The Center for Science in Public Interest did not express strong support or opposition to the registration of MON 863, but did provide a detailed analysis identifying perceived flaws in the Insect Resistance Management (IRM) plan. Foundation E.A.R.T.H., an environmental organization focusing on agriculture, supported approval of the registration based on an impact survey of 300 corn growers who, by and large, were interested in reducing pesticide use and using a seed product like MON 863. Greenpeace, The Sierra Club,

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and The Xerces Society, all environmental advocacy groups, along with the Union of Concerned Scientists, a public interest group, opposed approval of the application claiming that insufficient scientific data are available. Each of these groups provided lengthy comments and/or independent evaluations of the application materials submitted by Monsanto.

Agricultural trade associations generally supported approval of registration of MON 863. Among these trade associations were the American Seed Trade Association, the Agribusiness Association of Iowa, the Illinois Corn Growers Association, the Iowa Corn Growers Association, the Nebraska Corn Growers Association, the Iowa Seed Association, the National Grain and Feed Association, and the National Wild Turkey Federation. A representative of the National Corn Growers Association supported the registration and expressed the importance of a workable IRM plan. The Illinois Corn Growers Association expressed concerns about handling and marketing the product.

Approximately 20 seed and grain companies submitted comments in support of registration of MON 863. Entomologists from research and academic organizations including the NCR-46 committee (a technical committee of research and extension entomologists), Iowa State University, Kansas State University, Michigan State University, Pennsylvania State University, and the University of Delaware also expressed support of the registration. Government representatives of the Illinois Department of Agriculture, Illinois State Senate, Iowa Department of Agriculture, Nebraska Department of Agriculture, Ohio Department of Agriculture, Texas House of Representatives, Texas Senate, and U.S. Department of Agriculture all supported registration of MON 863.

BPPD will do a separate response to comment document that will be available at the time the registration decision is announced in the Federal Register. We anticipate this will be within approximately 30 days.

#### III. RATIONALE FOR RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. BPPD determines that all of the relevant criteria have been fulfilled.

BPPD determines that it is appropriate to conditionally register the MON 863 product under Section 3(c)(7)(C) because insufficient time has elapsed since the imposition of the data requirements for:

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- 1) Independent laboratory analytical method validation.
- 2) Cry3Bb1 protein expression data in terms of dry weight, as the amount of protein present in the given tissue.
- 3) Field degradation studies evaluating accumulation and persistence of Cry3Bb1 protein in several different soils in various strata.
- 4) Laboratory toxicity test with Orius insidiosus (minute pirate bug).
- 5) Laboratory toxicity test with carabid (ground beetle).
- 6) Laboratory toxicity test with *Tetraopes* (red milkweed beetle).
- 7) Intermediate and multi-year non-target organism field studies with statistical power.
- 8) A six week broiler dietary study.
- 9) Research regarding corn rootworm adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- 10) Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW.
- 11) Research regarding the mechanism of potential resistance of CRW to MON 863. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- 12) Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy.
- 13) Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is  $\leq 0.01$ .
- 14) Continuation of baseline susceptibility studies currently underway for WCRW and initiation for NCRW and monitoring techniques such as discriminating dose concentration assays, as well as investigation of their feasibility as resistance monitoring tools.

The applicant has submitted or cited data sufficient for BPPD to determine that conditional registration of MON 863 under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment, as discussed above. Monsanto Company submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to *Bacillus thuringiensis* Cry3Bb1 protein during the conditional registration is not expected to be significant. The data also demonstrate that there is virtually no possibility of any risk associated with weediness or outcrossing to wild relatives.

Registration of *Bacillus thuringiensis* Cry3bb1 protein and the genetic material necessary for its production (vector ZMIR3L) in event MON863 corn is in the public interest because MON 863 corn is less risky to human health and/or the environment than currently registered pesticides and the improved season long protection and practical benefits of ease of MON 863 use exceed those of the currently registered alternatives, most of which are restricted use products.— Specifically: 1) for the first 3 year, MON 863 is projected to reduce conventional pesticide use by 12.5 million lbs active ingredient on 7.5 million corn acres (0.1 carbamates, 3.5 pyrethroids, 3.0

organophosphates, and 0.9 for other chemical classes. This totals to 7.5 million acres of use reduction. To the extent that MON 863 is used on acreage that would be uneconomical to otherwise treat, the total use reduction would be less than the MON 863 acres adoption.)

2) it has a predicted yield benefit of 1.5 – 4.5% per acre greater than conventionally treated corn, 3) grower benefits are estimated at \$6.56 per acre vs. conventionally treated corn, 4) the total first 3 year economic benefits are estimated at \$49.2 million.

(EPA's public interest analysis considers three years of MON 863 use, because EPA has been informed that Monsanto will request that the current tolerance exemption for Cry 3bB1, which expires on May 1, 2004, be amended to remove the expiration date. If (1) Monsanto requests such an amendment to the Cry 3Bb1 tolerance exemption, (2) EPA grants such amendment request, and (3) Monsanto subsequently requests that the MON 863 registration be amended to expire at a later date, EPA currently believes that the data reviewed so far likely will support an extension of the conditional registration for an additional two years.)

In view of these minimal risks and the clear benefits related to YieldGard Rootworm, BPPD believes that the use of the product during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, BPPD recommends imposing the data requirements specified earlier in the attached Biopesticide Registration Action Document in Section III.

BPPD also believes, as explained in the attached BRAD section II.E., that the third criterion for a FIFRA 3(c)(7)(C) conditional registration has been fulfilled because the use of Cry3Bb1 corn under this registration would be in the public interest.

A tolerance exemption has been granted pursuant to FFDCA section 408(d) for *Bacillus* thuringiensis Cry3Bb1 protein and the genetic material necessary for its production in corn. However, this tolerance exemption expires in May 2004 and therefore, this registration would also expire in May 2004 until such time as the tolerance is permanent. At that time, the registration would be amended to expire in three years from the date of the original registration.

## IV. RECOMMENDATION

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of this registration. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

Based on the data submitted and cited by the applicants and reviewed by BPPD staff, the Biopesticides and Pollution Prevention Division recommends that the Monsanto Company Cry3Bb1 corn product containing the new active ingredient *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn be REGISTERED under FIFRA section 3(c)(7)(C), with appropriate limitations.

The expiration data of the registration has been set to match that of the tolerance exemption,

May 1, 2004.

CONCUR:

NONCONCUR:

DATE: 2/24/03

FEB 2.4 2003

#### MEMORANDUM

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Registrations for the Monsanto

Company Bt Corn Plant-Incorporated Protectant Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L)

in Event MON863 Corn: (EPA File Symbol 524-LEI)

-DECISION MEMORANDUM-

FROM:

Janet L. Andersen, Ph.D., Director

Biopesticides and Pollution Prevention Division

TO:

James J. Jones, Deputy Director

Office of Pesticide Programs

#### I. ISSUE

Should the Agency conditionally register Monsanto Company's Bt corn product pursuant to FIFRA §3(c)(7)(C)?

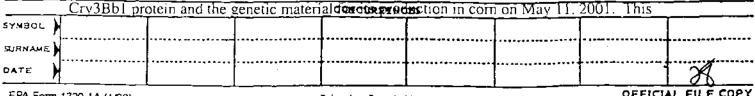
#### II. BACKGROUND

## Active Ingredient

Cry3Bb1 protein is a delta-endotoxin from *Bacillus thuringiensis* spp. *kumamotoensis* and has activity against certain beetles. The wild-type *cry3Bb1* gene was modified to enhance the protein's activity against the corn root worm complex.

## **EUPs and Tolerance Exemption**

Several experimental use permits and amendment/extensions have been granted by the Agency since April 2000 for different Cry3Bb1 corn plant-incorporated protectants, EPA EUP Numbers 524-EUP-90, -92, and -93. A tolerance exemption was established for *Bacillus thuringiensis* 



tolerance exemption was codified under 40 CFR Part 180.1214 and expires on May 1, 2004. Monsanto has indicated their intent to submit a petition amending the Cry3Bb1 com tolerance exemption to remove the expiration date once they obtain commercial approval.

## Registration Application and Public Comments

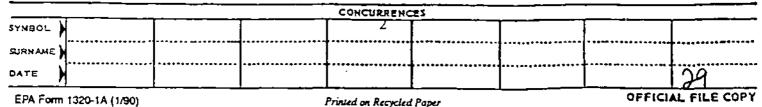
On March 1, 2001, EPA announced receipt of Monsanto's Event MON863 Cry3Bb1 corn seed increase registration application (EPA File Symbol 524-LEI) pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (66 FR 15435). On March 13, 2002, EPA announced receipt of a revised application from Monsanto for EPA File Symbol 524-LEI for full commercial use. Finally, on July 24, 2002, EPA announced a meeting of the FIFRA Scientific Advisory Panel (SAP) to consider and review corn rootworm plant-incorporated protectant insect resistance management and non-target insect issues (67 FR 48461).

Approximately 937 comments were received by EPA in response to these announcements. Comments were received from private citizens, independent farmers, farm cooperatives, farm industry representatives, trade organizations, advocacy groups, academic researchers, and government officials. Comments received included handwritten letters, typed letters, e-mails, faxes, and slide presentations from the SAP meeting.

Several organizations interested in the registration of MON 863 sponsored letter writing campaigns to promote their interests and provided form letters for members or other interested citizens to submit to EPA. Six master form letters were identified. The originating organizations for these campaign letters were not apparent, and the master letters were identified on the basis of the most consistently copied text. Most of the 937 comments received were form letters (81 percent). In some cases the form letters were signed and mailed without alteration. However, many commenters added personalized comments or edited the form letters to better express their individual views.

About 88 percent of the 937 comments were received from private citizens. Support or opposition of the registration was not tracked for individual commenters; however, all six of the master form letters expressed support for the registration of MON 863. Based on the large number of form letters received and the large number of letters received from private citizens, most of the private citizens who commented on the application generally support registration.

Some of the major environmental or public interest groups included the Center for Science in Public Interest, Foundation E.A.R.T.H., Greenpeace, The Sierra Club, The Xerces Society, and Union of Concerned Scientists. The Center for Science in Public Interest did not express strong support or opposition to the registration of MON 863, but did provide a detailed analysis identifying perceived flaws in the Insect Resistance Management (IRM) plan. Foundation E.A.R.T.H., an environmental organization focusing on agriculture, supported approval of the registration based on an impact survey of 300 corn growers who, by and large, were interested in reducing pesticide use and using a seed product like MON 863. Greenpeace, The Sierra Club,



and The Xerces Society, all environmental advocacy groups, along with the Union of Concerned Scientists, a public interest group, opposed approval of the application claiming that insufficient scientific data are available. Each of these groups provided lengthy comments and/or independent evaluations of the application materials submitted by Monsanto.

Agricultural trade associations generally supported approval of registration of MON 863. Among these trade associations were the American Seed Trade Association, the Agribusiness Association of Iowa, the Illinois Corn Growers Association, the Iowa Corn Growers Association, the Nebraska Corn Growers Association, the Iowa Seed Association, the National Grain and Feed Association, and the National Wild Turkey Federation. A representative of the National Corn Growers Association supported the registration and expressed the importance of a workable IRM plan. The Illinois Corn Growers Association expressed concerns about handling and marketing the product.

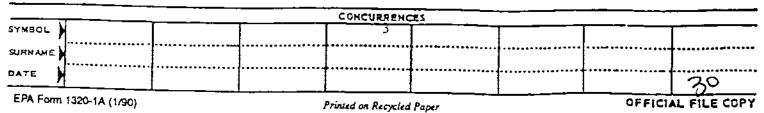
Approximately 20 seed and grain companies submitted comments in support of registration of MON 863. Entomologists from research and academic organizations including the NCR-46 committee (a technical committee of research and extension entomologists), Iowa State University, Kansas State University, Michigan State University, Pennsylvania State University, and the University of Delaware also expressed support of the registration. Government representatives of the Illinois Department of Agriculture, Illinois State Senate, Iowa Department of Agriculture, Nebraska Department of Agriculture, Ohio Department of Agriculture, Texas House of Representatives, Texas Senate, and U.S. Department of Agriculture all supported registration of MON 863.

BPPD will do a separate response to comment document that will be available at the time the registration decision is announced in the Federal Register. We anticipate this will be within approximately 30 days.

#### III. RATIONALE FOR RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. BPPD determines that all of the relevant criteria have been fulfilled.

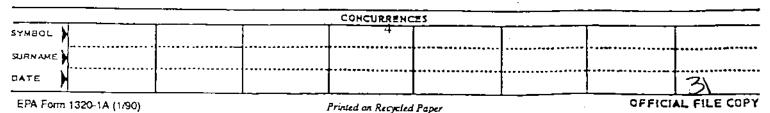
BPPD determines that it is appropriate to conditionally register the MON 863 product under Section 3(c)(7)(C) because insufficient time has elapsed since the imposition of the data requirements for:



- 1) Independent laboratory analytical method validation.
- 2) Cry3Bb1 protein expression data in terms of dry weight, as the amount of protein present in the given tissue.
- 3) Field degradation studies evaluating accumulation and persistence of Cry3Bb1 protein in several different soils in various strata.
- 4) Laboratory toxicity test with Orius insidiosus (minute pirate bug).
- 5) Laboratory toxicity test with carabid (ground beetle).
- 6) Laboratory toxicity test with *Tetraopes* (red milkweed beetle).
- 7) Intermediate and multi-year non-target organism field studies with statistical power.
- 8) A six week broiler dietary study.
- 9) Research regarding corn rootworm adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- 10) Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW.
- 11) Research regarding the mechanism of potential resistance of CRW to MON 863. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- 12) Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy.
- 13) Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is  $\leq 0.01$ .
- 14) Continuation of baseline susceptibility studies currently underway for WCRW and initiation for NCRW and monitoring techniques such as discriminating dose concentration assays, as well as investigation of their feasibility as resistance monitoring tools.

The applicant has submitted or cited data sufficient for BPPD to determine that conditional registration of MON 863 under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment, as discussed above. Monsanto Company submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to *Bacillus thuringiensis* Cry3Bb1 protein during the conditional registration is not expected to be significant. The data also demonstrate that there is virtually no possibility of any risk associated with weediness or outcrossing to wild relatives.

Registration of *Bacillus thuringiensis* Cry3bb1 protein and the genetic material necessary for its production (vector ZMIR3L) in event MON863 corn is in the public interest because MON 863 corn is less risky to human health and/or the environment than currently registered pesticides and the improved season long protection and practical benefits of ease of MON 863 use exceed those of the currently registered alternatives, most of which are restricted use products.— Specifically: 1) for the first 3 year, MON 863 is projected to reduce conventional pesticide use by 12.5 million lbs active ingredient on 7.5 million corn acres (0.1 carbamates, 3.5 pyrethroids, 3.0



organophosphates, and 0.9 for other chemical classes. This totals to 7.5 million acres of use reduction. To the extent that MON 863 is used on acreage that would be uneconomical to otherwise treat, the total use reduction would be less than the MON 863 acres adoption.)

2) it has a predicted yield benefit of 1.5 – 4.5% per acre greater than conventionally treated corn, 3) grower benefits are estimated at \$6.56 per acre vs. conventionally treated corn, 4) the total first 3 year economic benefits are estimated at \$49.2 million.

(EPA's public interest analysis considers three years of MON 863 use, because EPA has been informed that Monsanto will request that the current tolerance exemption for Cry 3bB1, which expires on May 1, 2004, be amended to remove the expiration date. If (1) Monsanto requests such an amendment to the Cry 3Bb1 tolerance exemption, (2) EPA grants such amendment request, and (3) Monsanto subsequently requests that the MON 863 registration be amended to expire at a later date, EPA currently believes that the data reviewed so far likely will support an extension of the conditional registration for an additional two years.)

In view of these minimal risks and the clear benefits related to YieldGard Rootworm, BPPD believes that the use of the product during the limited period of the conditional registration will not cause any unreasonable adverse effects.

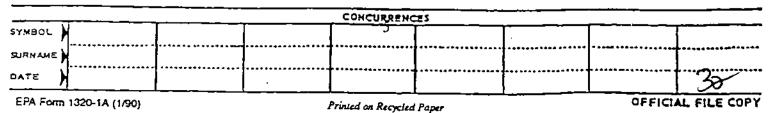
Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, BPPD recommends imposing the data requirements specified earlier in the attached Biopesticide Registration Action Document in Section III.

BPPD also believes, as explained in the attached BRAD section II.E., that the third criterion for a FIFRA 3(c)(7)(C) conditional registration has been fulfilled because the use of Cry3Bb1 corn under this registration would be in the public interest.

A tolerance exemption has been granted pursuant to FFDCA section 408(d) for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in com. However, this tolerance exemption expires in May 2004 and therefore, this registration would also expire in May 2004 until such time as the tolerance is permanent. At that time, the registration would be amended to expire in three years from the date of the original registration.

## IV. RECOMMENDATION

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of this registration. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.



Based on the data submitted and cited by the applicants and reviewed by BPPD staff, the Biopesticides and Pollution Prevention Division recommends that the Monsanto Company Cry3Bb1 corn product containing the new active ingredient Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn be REGISTERED under FIFRA section 3(c)(7)(C), with appropriate limitations.

The expiration data of the registration has been set to match that of the tolerance exemption,

May 1, 2004. CONCUR:

NONCONCUR

JOBMYZ SURNAME EPA Form 1320-1A (1/90)

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WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 1 4 2003

Dr. Russell P. Schneider Director, Regulatory Affairs Monsanto Company 600 13<sup>th</sup> Street, N.W. Suite 660 Washington, D.C. 20005

Dear Dr. Schneider:

Subject:

MON863 Cry3Bb1 Corn/ Pre-Acceptance Letter

EPA File Symbol 524-LEI

This is a pre-acceptance letter regarding Monsanto's application to register the above referenced product for a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Monsanto's product under FIFRA Section 3(c)(7)(C) provided Monsanto amends its application for registration by submitting the required information as described in this letter.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto submits the information in writing as described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that Monsanto agree in writing to the following.

1) The subject registration will automatically expire on midnight May 1, 2004. The registration must expire on this date because this is the date of expiration of the tolerance exemption under 40 CFR 180.1214. When and if the Agency registers this product, it is our understanding that Monsanto intends to submit in the near future an amendment application to modify the expiration date and a petition to amend the tolerance exemption under 40 CFR 180.1214 so that its expiration date is removed. Based on the Agency's review of the data submitted and cited in support of this application, and provided that the Agency finalizes a rule which amends 40 CFR 180.1214 so that its expiration date is removed; the Agency anticipates at this time that an

expiration date three years from the initial date of registration for this product would be appropriate.

- 2) The subject registration will be limited to Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn use in field corn.
- 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4) Submit production information for this product to Mr. Owen Beeder of Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October I and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.
- 5) Submit independent laboratory method validation (under OPPTS Guidelines 860.1340) to complete the database for Cry3Bb1 corn within 12 months of the date of registration. Provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a Cry3Bb1 analytical method within 6 months of the date of registration. The extraction and detection method as described for Cry3Bb1 protein appears to be adequate for analysis of Cry3Bb1 protein in corn grain. However, this method must be validated by both an independent laboratory and the EPA Biological and Economic Analysis Division laboratory before it can be considered a valid method. In addition, to assure that grain handlers have a test method in place prior to harvest, you must make available Cry3Bb1 strip tests to grain handlers and demonstrate to the Agency this provision prior to September 2003. EPA understands that these are 'qualitative' test kits and that you are in discussions with USDA/GIPSA about providing methodology and reagents for their use in developing a validated 'quantitative' method for MON 863 and that this transfer of materials will take place once registration occurs.
- 6) Submit expression data in terms of dry weight, as the amount of protein present in the given tissue. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data obtained for roots should also include typical times when corn rootworm would be feeding. Data are due within 24 months of the date of registration, provided the registration is amended to extend the registration date.
- 7) Submit field degradation studies evaluating accumulation and persistence of Cry3Bb1 in several different soils in various strata. Representative fields must have been planted with MON863 and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if Cry3Bb1 is accumulating or

persisting in soil samples. A protocol is due within 90 days of the date of registration, and a progress report is due within one year of the date of registration. If the registration and tolerance exemption are amended to extend the expiration dates, a final report is due two years from the date of registration.

- 8) Submit laboratory toxicity tests with *Orius insidiosus* (minute pirate bug), carabid (ground beetle), and *Tetraopes* (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.
- 9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (The carabid and nematode data are of particular interest.) and annual reports each year of this registration every April 30th.
- 10) Submit a six week broiler dietary study with 60% 70% MON 863 corn in the diet that is of appropriate duration to represent the start and growing periods of the test species. Balanced diets should be formulated according to the National Research Council guidelines ("Nutrient Requirements of Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.
- 11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.
  - Research regarding adult and larval movement and dispersal, mating habits, ovipositional
    patterns, number of times a female can mate and fecundity.
  - Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
  - Research regarding the mechanism of potential resistance of CRW to MON 863 must be
    determined to develop an appropriate long-term IRM strategy. Monsanto must attempt to
    develop resistant CRW colonies to aid in determining selection intensity.
  - Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
  - Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002

3b

letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is  $\leq 0.01$ .

- Baseline susceptibility studies currently underway should be continued for WCRW and initiated for NCRW and monitoring techniques such as discriminating dose concentration assays need to be thoroughly investigated for their feasibility as resistance monitoring tools.
- 12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 com on a wide scale.
- 13) You must commit to do the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 Bt corn has the following elements:

- 1] Requirements relating to creation of a non-Cry3Bb1 Bt corn refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 Bt corn;
- 2] Requirements for the registrants to prepare and require Cry3Bb1 Bt corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- 4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the Cry1 CAP);
- 5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;
- 6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Submit annual reports on sales(by state and county), IRM grower agreements results, compliance, and educational program on or before January 31<sup>st</sup> each year beginning in 2004.

#### a. Refuge Requirements

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-Cry3Bb1 Bt corn that
  may be treated with insecticides as needed to control corn rootworm larvae. Growers will not
  be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while
  adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips. If row strips within a corn field are implemented, then at least 6 and preferably 12 consecutive rows should be planted.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to
  growers will specify that insecticides labeled for control of corn rootworm adults cannot be
  applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar
  manner.

#### b. Grower Agreements

- 1] Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] The registrant must develop a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bi* comproduct will affirm annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.
- 4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating

to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

- 5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.
- 6] The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* MON863 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

#### c. IRM Education and IRM Compliance Monitoring Programs

- 1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* MON863 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* MON863 corn fields. The education program shall involve the use of multiple media, e.g. faceto-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* MON863 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Grower Association and state extension programs.
- 2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

- 3] Beginning January 31, 2004 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).
- 4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON863 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the Cry1 CAP. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5] 15] below.
- 5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON863 Bt corn.
- 6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of *Bt* corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
- 7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9] The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the



regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.

- 10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes.
- 11] The registrant shall train its representatives who make on-farm visits with MON863 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- 13] If a grower, who purchases MON863 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- 14] Beginning January 31, 2004 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- 15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

#### d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

1) The registrants will monitor for resistance and/or trends in increased tolerance for comrootworm. Sampling should be focused in those areas in which there is the highest risk of

resistance development. You must submit a protocol within 90 days of the date of registration.

- 2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.
- 3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.
- 5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30<sup>th</sup> each year for the duration of the conditional registration.

#### e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm must be submitted by 1/31/2004. If resistance is confirmed, all acres (MON863 Bt fields and non-Cry3Bb1 MON863 Bt refuges) should be treated with insecticides targeted at CRW adults as well as larvae.

#### Annual Reports:

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales	Reported by county and state summed by	January 31st each year
	state	beginning in 2004
	-12g	

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Grower Agreement	Number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	January 31st each year beginning in 2004
Grower Education	Education program completed previous year and plan for next year	January 31st each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31st each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15th each year and full report January 31st each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004

Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration
	M2	

IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 <sup>th</sup> each year

#### Label:

You must submit a revised label prior to further consideration of this registration application that includes the following statements.

The following information regarding commercial production must be included in the Grower Guide.

- Growers must plant a structured refuge of at least 20% non-Cry3Bb1 Bt corn that may be
  treated with insecticides as needed to control corn rootworm larvae. Growers will not be
  permitted to apply CRW labeled insecticides to the refuge for control of insect pests while
  adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips. If row strips within a corn field are implemented, then at least 6 and preferably 12 consecutive rows should be planted.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to
  growers will specify that insecticides labeled for control of corn rootworm adults cannot be
  applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar
  manner.

This letter does not mean that EPA agrees to amend the subject product. If Monsanto submits the information in writing as described in this letter, however, EPA will be able to continue to process the amendment application.

Sincerely,

Janet L. Andersen, Ph.D, Director Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

<u>i</u>

Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20005
PHONE (202) 783-2460
FAX (202) 783-2468
bttp://www.monsanto.com

February 20, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863

EPA File Symbol 524-LEI

Dear Mr. Hutton:

In support of our application to register Corn Event MON 863 we are submitting a revised data matrix, label and Confidential Statement of Formula. Contained within the Data Matrix are numerous requests for data waivers. These waiver requests are based primarily on the low potential for exposure to Cry3Bb1 protein and the fact that many of microbial pesticide data requirements (49 CFR 158.740) are not applicable to a plant-incorporated protectant.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)

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- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the confidential attachment, Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D.

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Mr. P. Hutton 2/20/2003 Page 2 of 45

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD

Russell Schneider, Monsanto

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		·		
·	·			

OPP Identifier

Environmental	ed States Protection Agency ton, DC 20460
Application	n for Pesticide – S
ymbol 524-LEI	2. EPA Product Ph
vent MON 863	PM #
t (Include ZIP Code)	6. Expedited product is simila EPA Reg. No.
	Environmental Washing  Application  ymbol 524-LEI  yent MON 863 (Include ZIP Code)

<b>≎</b> EPA	Environmer Was	United States  Ital Protect  shington, DC 2	tion Agenc	у		_	stration ndment ier	OPP Identifier Number
	Applica	tion for P	<u>esticide - S</u>	Section I				
Company/Product Number     File Sym	bol 524-LEI		2. EPA Product Ph	Manager Aillip O. Hu	itton		3. Propos	ed Classification
Company/Product (Name) Corn Even	t MON 863	<u> </u>	PM #	90			<b>I</b> ⊠ Nor	ne Restricted
5. Name and Address of Applicant (In Monsanto Company 600 13 <sup>th</sup> St., N.W., Suite 660 Washington, DC 20005	clude ZIP Code)	-	product is simila EPA Reg. No. Product Name	ar or identical	in com	position	and labeling to	
	<del></del>	Sect	<u>ion – II </u>					
Amendment – Explain  Resubmission in resp  Notification – Explain  Explanation: Use additional page(s	onse to Agency letter da		ion II.)	Final printed Agency lette "Me Too" Ap Other – Exp	er dateo optication	d on.	onse to	·
Submission of request for data Corn Event MON 863	waivers and revise	ed data matri	x, labeling and	CSF in su	pport	of app	olication to r	egister
		Secti	ion – III		•			
1. Material This Product Will Be Pa Child Resistant Packaging Yes* No * Certification must ' submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per Container	Water Soluble Pa Yes No If "Yes" Package wgt.	No. per Container			e of Container Metal Plastic Glass Paper Other	
Location of Net Contents Informatio     Label Container	n j	4. Size(s) Reta	il Container	·		On Lab	of Label Direction	
6. Manner in Which Label is Affixed to	Product	Lithograp Paper glu Stenciled	red 	Other				
			ion – IV	<del></del> -				
1. Contact Point (Complete items direct Name Russell P. Sch		Title	Regulatory Al					(Include Area Code) 83-2860
I certify that the statements I hav I acknowledge that any knowingl both under applicable law.	e made on this form and							6. Date Application Received (Stamped)
2. Signature Ward 140		3. Title	Regulatory A	Affairs Man	ager		ļ	, , ,
4. Typed Name	Tel. (636) 737-663	5. Date	February 20,	2003				48

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WASHINGTON, D.C. 20460

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burden to Director, OPPE Information Management Division (2137), U. Do not send the completed form to this address.	S. Environmental Protection	Agency, 401 M Street, S.W., Washington DC, 20460.			
Certification with I	Respect to Citation	of Data			
Applicant's/Registrant's Name, Address, and Telephone Number:	·	EPA Registration Number / File Symbol:			
Monsanto Company, 600 13th Street, N.W., Washington, DC 2	005 (202) 383-2866	524-LEI			
Active Ingredient(s) and/or representative test compound(s): B.t. Cry31 necessary for its production (vector ZMIR13L) in event MON 863 co.		Date: February 20, 2003			
General Use Pattern(s) (list all those claimed for this product using 40 to	CFR Part 158:	Product Name:			
Terrestrial field crop	Corn Event MON 863				
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption					
I am responding to a Data-Catt-in Notice, and have included w should be used for this purpose).	rith this form a list of compa	nies sent offers of compensation (the Data Matrix form			
Section I: METHOD OF DA	TA SUPPORT (Ched	k one method only)			
I am using the cite-all method of support, and have included with this form a list of companies set offers of compensation (the Data Matrix Form should be used for this purpose).  I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).					
Section II: GEI	NERAL OFFER TO	PAY			
(Required if using the cite-all method or when using the cite-al		_ · _ <del> </del>			
f hereby offer and agree to pay compensation, to other person	s, with regard to the approv	al of this application, to the extent required by FIFRA.			
<del></del>	: CERTIFICATION				
I certify that this application for registration, this form for reregistration for registration for registration, or the Data-Cal method is indicated in Section 1, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie under the data requirements in effect on the date of approval of this appsimilar composition and uses.	I-In response. In addition, it a in the Agency's files that ( nts in this product; and (2) i	the cite-all option or cite-all option under the selective 1) concern the properties or effects of this product or s a type of data that would be required to be submitted			
ficertify that for each exclusive use study cited in support of thi obtained the written permission of the original data submitter to cite that		on, that I am the original data submitter or that I have			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (f) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.					
I certify that the statements I have made on this form and alknowingly false of misleading statement may be punishable by fin	e are action and a second of the control of the con	e, accurate, and complete. I acknowledge that any under the applicable law.			
Signature	Date	Typed or Printed Name and Tille			
D. Ward re	February 20, 2003	Dennis P. Ward, Regulatory Affairs Manager			

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00-CR-032E-19

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401 W Siteet, S. VV., Washington	n, OC 20460. Do not send the form to this address.	ATA MATRIX	<del></del>	<del></del>	-	
Date: February 20, 2003		NA WALLIA		EPA Reg. No./File Symb		E[ Page tof 14
Applicant's/Pegistrant's Name &	Address:	<del></del> -				
	Street, N.W., Suite 660, Washington, D.C. 2000:	5		Product: Corn Event	MON 863	
Ingredient Bacillus Huring	iensis Cry3Bb1 and the genetic material necessary	for its production	(vector ZMIR (3L) in	event MON 863 corn		<del></del> -
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Sta	atus	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrater of a Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	.  Monsanto Com	rany O	WN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTH Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300.	455382-09	Monsanto Com	pany O'	wn	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Mittanck and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152.	454240- <u>02</u>	Monsanto Com	oany O	wn	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodelectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223.	454240-07	Monsanto Com	запу О	wn	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Comp	<del></del>	wn	Dated May 21, 2001
Signature N. Wal	7) Flactonia and Sance varsions qualitable. Submit only	,	Name and Title Dennis P. Ward, Ph. Regulatory Affairs M	∕lgr		ernal ilsa Conv

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	Da	ATA MATRIX			
Date: February 20, 2003			· ·	EPA Reg. No./File Symbol: 524-LE	Page 2 of 14
	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000.			Product: Corn Event MON 863	
Ingredient Bacillus thurir	giensis Cry3Bb1 and the genetic material necessur	y for its productio	n (vector ZMIR13L) in e	event MON 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of Bacillus thuringiensis Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Com; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance,	451568-00	.  Monsanto Compa	ny OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for Bacillus thuringiensis Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active	PP 7F4888	Monsanto Compa	iny OWN	Dated June 24, 1997
151-26 885.2100	Pilneinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bacillus thuringiensis Corn Rootworm Control Protein, as Produced in the Corn (Zea mays, L.), and the Amendment to the Previous	449043-00	Monsanto Compa		Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Corn Event MON 863. MSL-17137.	454240-10	Monsanto Compa	iny <u>QWN</u>	Dated   May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Tachniques, ASSI, 1715.	454240-11	Monsanto Compa	usyOWN_	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs M	i i	

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Date: February 20, 2003		- <del>-</del>		EPA Reg. No./File Symbol: 524-	LEI Page 3 of 14
	3th Street, N.W., Suite 660, Washington, D.C. 2000			Product: Corn Event MON 80	63
Ingredient Bacillus thuri	ingiensis Cry3Bb1 and the genetic material necessar	y for its production	(vector ZMIR13L) in	event MON 863 corn	,
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Ifileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by E. coli Fermentation and Corn Event MON 863. MSL-17274.	455382-01	Monsanto Compa	any OWN	Dated November 5, 2001
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Com Grain.	453731-01	Мопѕапто Сотра	any OWN	Dated April 7, 2001
151-27 885.2400	Samples will be submitted as part of the independent laboratory method validation work that is ongoing.	12.2			
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.r. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Com Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Compa	anyOWN	Dated May 21, 2001
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	454240-09	Мопзаню Сотра	any OWN	Dated May 21, 2001
Signature	.07) Flortragic and Paper versions available. Submit only		Name and Title Dennis P. Ward, Ph.I. Regulatory Affairs M	lgr.	Internal Hea Copy

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Date: February 20, 2003	P. A. January			EPA Reg. No	o./File Symbol: 524-LEI	Page 4 of 14
	3th Street, N.W., Suite 660, Washington, D.C. 2000			<del></del>	Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material necessa	<del></del>	<del></del>			
Guideline Reference Number	Guideline Study Name	MRID Number	- Submitter	·	Status	Note
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with E. coli-Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382. A pathogenicity determination is not applicable since Cry3Bb1 is not a fiving organism.	455382-02	Munsanto Com	pany	OWN	Dated November 5, 2001
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001).  Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1  Protein Purified from Corn Event MON 863 and  Cry3Bb1 Protein Purified from E. coli. MSL-17292. A  pathogenicity determination is not applicable since  Cry3Bb1 in not a living paymains.	455382-03	Monsanto Com	ipany	OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the <i>in vitra</i> Digestibility of Cry3bBb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MS1, 17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-02	Monsanto Con	рапу	own	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3861 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for dermal or ocular contact.					
152-32 885.3150 ·	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.					
Signature			Name and Title Dennis P. Ward, Pl Regulatory Affairs		Date February 20, 2003	

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• •	D.	ATA MATRIX				
Date: February 20, 2003				EPA Reg. N	lo./File Symbol: 524-LEI	Page 5 of 14
Applicant's/Registrant's Name		5			" MON 863	
	3th Street, N.W., Suite 660, Washington, D.C. 2000		7 77 (U) 1 21 ) 1	1	Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material necessar		Τ'			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
152-33 885.3200	Not applicable since Cry3fib1 protein is neither infective not pathogenic.					
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140.	454240-08	Monsunto Com	pany	own	Dated May 21, 2001
152.36 152-37 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to <i>Bi</i> crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.					
152-39 885.3500	Not applicable since Cry3lbb1 is not a living organism.		,			
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999).  Bacillus thuringiensis Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwlite.  MSL-16161. A pathogenicity determination is not applicable since Cry3Bh1 is not a living organism.	449043-15	Monsanto Com	pany	own	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N		Date February 20, 2003	

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	D	ATA MATRIX			
Date: February 20, 2003				EPA Reg. No./File Symbol: 5	524-LEI Page 6 of 14
Applicant's/Registrant's Name (	& Address: 3th Street, N.W., Suite 660, Washington, D.C. 2000	5		Product: Corn Event MO	
Ingredient Bacillus thuris	igiensis Cry3Bb1 and the genetic material necessar	y for its production	n (vector ZMIR13L) in	event MON 863 corn	<u> </u>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17 885.4100	A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry3Bb1 is not a fiving organism.			į	
154-19 885.4200	Li, M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Com Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-19	Monsanto Comp	oany OWN	Dated August 19, 1999
154.19 885.2600	McKee, M.J. (2001) Hiuegill Dietary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383.	455382-00	Monsanto Comp	oanyOWN	Dated November 5, 2001
154-20 885.4240	Drottar, K.R. and H.O. Krueger (1999). Bacillus thuringlensis Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna). MSL-15988. A pathogenicity determination is not applicable since Cry3Hb1 is not a flying examine.	449043-18	Monsanto Conq		Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	· · · · · · · · · · · · · · · · · · ·	2003

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Date: February 20, 2003 Applicant's/Registrant's Name	P. Address:			EPA Reg. N	to./File Symbol: 524-LE	Page 7 of 14
	3 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	5		Product: (	Corn Event MON 863	·
Ingredient Bacillus thurii	agiensis Cry3Bb1 and the genetic material necessar	y for its productio	n (vector ZMIR13L) ii	event MOI	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-21 885.4280	Results of acute toxicity tests with <i>Daphuia</i> and catfish did not produce any evidence of adverse effects. Testing with estuarine and marine species is not warranted because of very low to no potential for exposure to the Cry3 protein from field corn. A pathogenicity					
	determination is not applicable since cry3Hb1 is not a living organism.					
154-22 885.4300	Cry3Bb1 is an insect toxin and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weedy wild relatives is virtually nonexistent.					
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (Hippodamia convergens). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-14	Monsanto Com	pany	OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999).  Bacillus thuringiensis Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate.  MSL-16162. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-16	Monsanto Com	pany	OWN	Dated August 19, 1999
Signature		-	Name and Title Dennis P. Ward, Ph Regulatory Affairs N		Date February 20, 2003	<del></del>

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Date: Pohreary 20, 2003				PA Reg. No./File Symbol: 524-I	LEI Page 8 of 14
Applicant's/Registrant's Name I		_			'
<del></del>	3th Street, N.W., Suite 660, Washington, D.C. 2000	<u>_</u>	<del></del>	roduct: Corn Event MON 86	53
Ingredient Bacillus thurii	igiensis Cry3Bb1 and the genetic material necessar	y for its productio	n (vector ZMIR13L) in e	vent MON 863 corn	
Guideline Reference Number	Guideline Study Name	MAID Number	Submitter	Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Cottembola ( <i>Folsomia candida</i> ). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-}7	Monsanio Compan	ıy OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with Green Lacewing Larvae (Chrysoperta carnea). MSL-16165. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12_	Monsanto Compan	ıy <u>OWN</u>	Dated August 19, 1999
154-23 885.4340	Palmer, S.I. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with the Parasitic Hymenoptera (Nasania vitripennis). MSL-1616. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-13	Monsanto Compan	own	Dated August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453484-02	Monsanto Compar	ıy OWN	Dated February 20, 2001
154-23 885.4340	Duan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic Bacillus thuringiensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle. Coleomegilla maculata. MSL-16936. A pathogenicity determination is not applicable since Cry3Bb1, in not a living greatlern.	453613-01	Monsanto Compar		Dated March 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mg	i -	3

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Date: February 20, 2003			·	EPA Reg. N	lo./File Symbol: 524-LE	Page 9 of 14
Applicant's/Registrant's Name &	s Address: p <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000.	<b>c</b>		One of the Atlanta	Corn Event MON 863	
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<del></del>	rgiensis Cry3Bb1 and the genetic material necessor	<u> </u>	<del></del>			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, Hippodamia convergens. MSL-17171. A pathogenicity determination is not applicable since Cry3Bb1 is not a	453613-02	Monsanto Com	DARV	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Com Rostworm Insect-Protected Com on Non-Target Organisms. MSL-17179. A pathogenicity determination is not applicable since.	455382-06	Monsanto Com		OWN	Dated November 5, 200
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic Bacillus thuringiensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, Coleonegilla maculata. MSL-16907. A pathogenicity determination is not conflictly piene Cry3Bb1 in part diving properior.	455382-04	Monsanto Com	sany	own	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Matilla (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (Danus plexippus) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since Cry3Bb1 in not a Butter property.	455382-05_	Monsanto Com	pany	OWN	Dated November 5, 2001
154-23 885.4340	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein in vitro. C3NTO. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Com	рапу	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs M		Date February 20, 2003	

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	D	ATA MATRIX				
Date: February 20, 2003				EPA Reg. f	No./File Symbol: 524-LEI	Page 10 of 14
Applicant's/Registrant's Name &		<del></del>		1	<u> </u>	
Monsanto Company,:600 13	3th Street, N.W., Suite 660, Washington, D.C. 2000.	5		Product:	Corn Event MON 863	
Ingredient Bacillus thurin	igiensis Cry3Bb1 and the genetic material necessar	y for its production	n (vector ZMIR13L) i	n event MO	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	. Submitter	′	Status	Note
154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-03	Monsanto Com	npany	OWN	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	456530-03	Monsanto Com	ірапу	OWN	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials.		Monsanto Com	прапу	OWN	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Con	ipany	OWN	Dated September 10, 2002
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified Bacillus thuringiensis Protein 11231 on Honey Bee Larvae. MSL-16168. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-10	Monsanto Con	ากากง	own _	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Pl Regulatory Affairs	ı.D.	Date February 20, 2003	

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<b>■</b> 4	D	ATA MATRIX				
Date: Pebruary 20, 2003 Applicant's/Registrant's Name 8				EPA Reg. f	No./File Symbol: 524-LEI	Page II of I4
- Applicant s/Hegistrant's Name & - Monsanto Company -600-13	a Address: <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	5		Product:	Corn Event MON 863	
<del></del>	giensis Cry3Bb1 and the genetic material necessar		on (vector ZMIR13L) in			
Guideline Reference Number	Guideline Study Name	MAID Number	. Submitter		Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified Bacillus thuringiensis Protein 11231 on Adult Honey Bees (Apis mellifera L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Com	pany	OWN	Dated August 19, 1999
885.5200	Martin, J.W., M.I. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the B.t. Protein 11098 as a Component of Insect Protected Corn. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Com	pany	own	Dated June 20, 2000
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> . Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected Corn Event MON 863. MSI-17102.		Monsanto Com	pany	OWN	Dated September 10, 2002
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bacillus thuringiensis Cry3Hb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors 2009) 121 (2009) 2017 (2009) 1413	450297-01	Monsanto Com	рапу	OWN	Dated January 13, 2000
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Com	pany ·	OWN	Dated February 20, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I	-	Date February 20, 2003	·

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	3th Street, N.W., Suite 660, Washington, D.C. 2000	)5		Product:	Corn Event MON 863	
	igiensis Cry3Bb1 and the genetic material necessar		r (vector ZMIR13L) i	n event MO	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	·	Status	Note
	Pilcher, C.D., J.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Hybrids as Determined in Year 2000 Field Trials.	453484-03	Monsanto Com	pany	OWN	Dated February 20, 2001
· · · · · · · · · · · · · · · · · · ·	Pitcher, C.D. (2001). Efficacy of MON 863 Against Com Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials.	453613-03	Monsanto Com	<u>pany</u>	OWN	Dated March 20, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	454240-00	Monsanto Com	рапу	own	Dated May 21, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	455382-00	Monsanto Com	spany	OWN	Dated November 5, 2001
	Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (Diabrotica barberi), Southern Corn Rootworm (D. undecimpunctata howardi), and Western Corn Rootworm (D. undecimpunctata howardi), ACC BUT!	455382-08	Monsanto Corr	прапу	Own	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs		Date February 20, 2003	

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Date: February 20, 2003				EPA Rea. No./	File Symbol: 524-LEI	Page 13 of 14
Applicant's/Registrant's Name &	Address:				· · · · · · · · · · · · · · · · · · ·	— . J. <u></u>
Monsanto Company, 600 13	3th Street, N.W., Suite 660, Washington, D.C. 2000	5	-	Product: Co	rn Event MON 863	
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material necessar	ry for its production	on (vector ZMIR13L) in	event MON 8	363 corn	
Guideline Reference Number	Guideline Study Name	MAID Number	. Submitter		Status	Note
······································	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556.	455770-01	Monsanto Comp	na <b>n</b> y	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of Bacillus thuringiensis Cry3Bbl Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766.	456530-01	Monsanto Comp	рапу	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Corn Event MON 863. MSL-17782.	456530-02	Monsanto Comp	any	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield Rootworm, MSL-17993.	456923-01	Monsanto Comp	any	OWN	Dated June 10, 2002
		<u> </u>		·····		
151,20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotiansferase II as a Plant Pesticide Formulation Inert Ingredient. 93-132E	430547-00	Monsanto Comp		OWN	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	D E	Date February 20, 2003	
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Date: February 20, 2003			· · · · · · · · · · · · · · · · · · ·	EPA Reg. No	o./File Symbol: 524-LEI	Page 14 of 14
	3th Street, N.W., Suite 660, Washington, D.C. 2000				Corn Event MON 863	<del></del>
	ngiensis Cry3Bb1 and the genetic material necessar	<del></del>	<del>,</del>	<u> </u>		
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	· 	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTii) in Albino Mice. ML-91-409. A pathogenicity determination is not applicable since Cry318b1 is not a living organism.	430547-01	Monsanto Con	pany	OWN	Dated November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in In vitro Mammatian Digestion Models. IRC-91-ANA-06. A pathogenicity determination is not applicable since Cry3Bh1 is not a living organism.	430933-02	Monsanto Com	рапу	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	Monsanto Com	ърапу	PL	Dated November 23, 1993
			**************************************			
Signature			Name and Title Dennis P. Ward, Pl Regulatory Affairs		Date February 20, 2003	<del>-</del>



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Washington, D.C. 20460

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ate: Fehruary 20, 2003			. £PA Reg. No	./File Symbol: 524-	LEI Page 1 of 1
	th Street, N.W., Suite 660, Washington, D.C. 20		Product: Co	orn Event MON 86	
•	giensis Cry3Bb1 and the genetic material neces	1 1 1			<u>-</u> -
uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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				2001	Dated
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			Monsanto Company	own	Dated November 5, 2
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Monsanto Company

Name and Title

Dennis P. Ward, Ph.D.

Regulatory Affairs Mgr.

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Dated

May 21, 2001



Signature

OWN

February 20, 2003

Date

Form Approved OMB No. 2070-0060



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Washington, D.C. 20460

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	DATA MATRIX			
Date: February 20, 2003		EPA	Reg. No./File Symbol: 524-LE1	Page 2 of 14
Applicant's/Registrant's Name & Address: Monsanto Company, 600-13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20			uct: Corn Event MON 863	
Ingredient Bacillus ihuringiensis Cry3Bb1 and the genetic material neces	sary for its production	(vector ZMIR13L) in even	t MON 863 corn	
Guideline Reference Number   Guideline Study Name	MRID Number	Submitter	Slatus	Note
		Monsanto Company	OWN	Dated June 20, 2000
		Monsanto Company —	OWN	Dated June 24, 1997
		Monsanto Company	OWN	Dated August 19, 199
		Monsanto Company	OWN	Dated May 21, 2001
		Monsanto Company	OWN	Dated *4ay 21, 2001
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2002	

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Date: February 20, 2003				EPA Reg. No./File Symbol: 52	4-LEI   Page 3 of 14		
Applicant's/Registrant's Name &	Address:		111111111111111111111111111111111111111	······································	<del></del>		
	3th Street, N.W., Suite 660, Washington, D.C. 2000			Product: Corn Event MON 863			
Ingredient Bacillus thurin	ngiensis Cry3Bb1 and the genetic material necessar	<del>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</del>	n (vector ZMIR13L) in	event MON 863 corn			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
			Monsanto Comp	any OWN	Dated November 5, 200		
			Monsanto Comp	any OWN	Dated April 7, 2001		
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			Monsanto Comp	any OWN	May 21, 2001		
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Signature			Name and Title Dennis P. Ward, Ph.: Regulatory Affairs M	Date D. February 20, 200	• •		

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	Address:  th Street, N.W., Suite 660, Washington, D.C. 20 giensis Cry3Bb1 and the genetic material neces		<del>, , , , , —, , , , , , , , , , , , , , </del>	duct: Corn Event MON 863	1
ngredient Bacillus thurin Buideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
c.			Monsanto Company	OWN	Dated November 5, 200
			Monsanto Company	OWN	Dated November 5, 200
			Monsanto Company	OWN	Dated January 8, 200
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Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	I.;,

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	D.	ATA MATRIX	<del></del>			
Date: February 20, 2003				EPA Reg. No./File Sy	mbol: 524-LEI	Page 5 of 14
Applicant's/Registrant's Name & Address:  Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005				Product: Corn Event MON 863		
	ngiensis Cry3Bb1 and the genetic material necessar		(vector ZMIR13L) in	event MON 863 co	FN	
Guidelina Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
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			Monsanto Comp		CWN .	August 19, 199
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		•	Dennis P. Ward, Ph.I		ry 30, 2003	
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Date: February 20, 2003			EPAI	Reg. No./File Symbot: 524-LEI	Page 6 of 14
Applicant's/Registrant's Name &	Address: th Street, N.W.; Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863		
	giensis Cry3Bb1 and the genetic material necessary				****
Guideline Reference Number	Guidetine Study Name	MRID Number	Submitter	Status	Note
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			Monsanto Company	OWN	August 19, 199
			Monsanto Company	OWN I	Dated November 5, 200
			Monsanto Company	CVA	Dated August 19, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	:

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	3th Street, N.W., Suite 660, Washington, D.C. 2000	<del></del>	Product: Corn Event MON 863		
Ingredient Bacillus thurir Guideline Reference Number	giensis Cry3Bb1 and the genetic material necessar  Guideline Study Name	y for its production  MRID Number	n (Vector ZMIRT3L) in e Submitter	Status	Note
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			Monsanto Compan	y <u>OWN</u>	August 19, 1999
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Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mg		# 1 # 2

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Applicant's/Registrant's Name &					······
	th Street, N.W., Suite 660, Washington, D.C. 2000		<del></del>	roduct: Corn Event MON 863	<del></del>
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material necessa	ry for its production	<del>' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' </del>	vent MON 863 corn	
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			Monsanto Compan	<del></del>	March 20, 200
Signature			Name and Title	Date	
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Date: February 20, 2003				EPA Reg. No./File Symbol: 524-I	LEI Page 9 of 14
Applicant's/Registrant's Name					
<del></del> -	3th Street, N.W., Suite 660, Washington, D.C. 2000			Product: Corn Event MON 863	
<del></del>	ngiensis Cry3Bb1 and the genetic material necessa	ry for its production	(vector ZMIR13L) in	event MON 863 corn	
Buideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanio Comp	any OWN	Dated March 20, 2001
			Monsanto Comp	any OWN	Dated November 5, 200
			Monsanto Comp	any OWN	Dated November 5, 200
			Monsanto Comp	any OWN	Dated November 5, 200
			Monsanto Comp		Dated November 5, 200
lignature			Name and Title Dennis P. Ward, Ph.I Regulatory Affairs M	Date Date February 26, 2003	

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Date: February 20, 2003 Applicant's/Registrant's Name & Address:		EPA Reg. No./File Symbol: 524-I	El Page 10 of 1
Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863	
Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material necessary for its pro-		event MON 863 corn	····
Guidetine Reference Number	umber Submitter	Status	Note
	Monsanto Com	pany OWN	Dated January 8, 2002
	Monsanto Com	pany OWN	Dated April 9, 2002
	Monșanto Com	pany OWN	Dated September 10, 2002
	Monsanto Com	pany OWN	Dated September 10, 2002
	Monsanto Com		Dated
Signature  EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper versions.	Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	1 -	

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		DATA MATRIX			
Date: February 20, 2003			EPA Reg.	No./File Symbol: 524-LEI	Page II of I
Applicant's/Registrant's Name 8					
	th Street, N.W., Suite 660, Washington, D.C. 2000			Corn Event MON 863	<del> </del>
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material necessar	y for its production	(vector ZMIR13L) in event MO	N 863 coru	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 199
			Monsanto Company	OWN	Dated June 20, 2000
				OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated January 13, 200
				0.73	Dated
Signature			Monsanto Company Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003.	February 20, 20

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
	n mar and a second of the seco		Monsanto Com	pany	OWN	Dated February 20, 200
			Monsanto Com	pany	OWN	Dated March 20, 2001
			Моляаню Сон	pany	OWN	Dated May 21, 2001
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			Monsanto Com	pany	OWN	November 5, 200
			Monsanto Com	pany	<u> </u>	Hovember 5, 200
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs N	.D.	Date February 20, 2003	

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Date: February 20, 2003			EPA Reg.	No./File Symbol: 524-LE	Page 13 of I
	& Address: 3 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20 Igiensis Cry3Bb1 and the genetic material necess			Corn Event MON 863	
Guidelina Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	own	Dated April 9, 2002
			Monsanto Company	OWN	Dated June 10, 2002
			Monsanto Company	CALIS	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2063	

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Date: February 20, 2003	·		EPA Reg	No./File Symbol: 524-LEI	Page 14 of 1-
Applicant's/Registrant's Name	& Address:				<del>.</del>
	3th Street, N.W., Suite 660, Washington, D.C.			Corn Event MON 863	
<del></del>	giensis Cry3Bb1 and the genetic material no	·			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	. Dated November 23. +993
			Монѕаню Сопірапу	OWN	Dated November 23, 1992
			Monsanto Company	PL.	Dated November 23, 4993
AT:					
Signature		a	ame and Title ennis P. Ward, Ph.D. egulatory Affairs Mgr.	Datu February 20, 2003	

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### CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

75

#### CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

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### PRODUCT LABEL

Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn' are attached. This label supersedes the label previously submitted to EPA, dated February 11, 2003.



### Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: YieldGard® Rootworm: Rootworm Protection]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

### Active Ingredient:

#### Other Ingredients:

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

### **CAUTION**

YieldGard is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

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#### **Insect Resistance Management**

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

### Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western com rootworm (Diabrotica virgifera virgifera) Northern com rootworm (Diabrotica barberi) Mexican com rootworm (Diabrotica virgifera zeae)



# CONFIDENTIAL ATTACHMENT



Amendment of the Application to Register a Bacillus thuringiensis
Cry3Bb1 Protein and the Genetic Material Necessary for its
Production (Vector ZMIR13L) in Event MON 863 Corn;
EPA File Symbol 524-LEI

#### **CONFIDENTIAL ATTACHMENT**

### **AUTHOR**

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

### DATE

February 20, 2003

### SUBMITTING REGISTRANT

Monsanto Company 600 13<sup>th</sup> Street N.W. Suite 660 Washington, DC 20005

#### MONSANTO REFERENCE No.

00-CR-032E-17

: 44

### . CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

Pages	Reason for Deletion	FIFRA Reference
37 & 38	Discloses commercial information	§10(d)(1)(A), (B) or (C)





Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 MOREANTO COMPANY
600 (3TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
PHONE (202) 783-2460
FAX (202) 783-2468
http://www.monsanto.com

February 20, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

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FEB 2 6 2003

OPP/BPPD

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863

EPA File Symbol 524-LEI

Dear Mr. Hutton:

- - - ·

In support of our application to register Corn Event MON 863 we are submitting a revised data matrix, label and Confidential Statement of Formula. Contained within the Data Matrix are numerous requests for data waivers. These waiver requests are based primarily on the low potential for exposure to Cry3Bb1 protein and the fact that many of microbial pesticide data requirements (49 CFR 158.740) are not applicable to a plant-incorporated protectant.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the confidential attachment, Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Denrus P. Ward, Ph.D.

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Mr. P. Hutton 2/20/2003 Page 2 of 45

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto



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<del></del>	Applic	ation for P	esticide - S						
1. Company/Product Number File Syrr	ibol 524-LEI		2. EPA Produc	t Manager nillip O. Hu	itton		3. Propos	sed Clas	sification
Company/Product (Name) Com Even	it MON 863	,	PM #	90			⊠ <sub>№</sub>	пе 🔼	Restricted
5. Name and Address of Applicant (Ir Monsanto Company 600 13 <sup>th</sup> St., N.W., Suite 660 Washington, DC 20005	clude ZIP Code)		6. Expedited product is similar EPA Reg. No.	ar or identical	in comp	osition and	l labeling to	<b>)</b> ;	-
Check if this is a new address			<u> </u>						 
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Notification – Explain	below.		لِكا	Other – Exp	ilain belo	)W.			
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1. Contact Point (Complete items dire	ctly below for identifica	tion of individual	to be contacted, i	l necessary, to	o proces	s this appl	ication.)		
Name Russell P. Sci	hneider	Title	Regulatory A	ffairs Direc	tor	Tele	phone No. (202) 38		Area Code) 66
I certify that the statements I have I acknowledge that any knowing	re made on this form an		s thereto are true,	accurate and	comple	te.	<del></del>		Application
both under applicable law.								(Stam	ped)
2. Signature Ward /40		3. Title	Regulatory A	Affairs Man	nager				
4. Typed Name Dennis P. Ward	Tel. (636) 737-663	5. Date	February 20,	2003					
EPA Form 8570-1 (Rev. 3-9	4) Previous editions a	re obsolete.	White - EP	A Fite Copy (	original	) Yellov	v - Applica	nt Copy	
Monsanto Company		00-CR-03	2E-19						3 of 45

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	gency, 401 M Street, S.W., Washington DC, 20460.						
Respect to Citation o	f Data						
Applicant's/Registrant's Name, Address, and Telephone Number:							
2005 (202) 383-2866	524-LEI						
	Oate: February 20, 2003						
CFR Part 158:	Product Name:						
	Corn Event MON 863						
	ed for all the same uses on your label, you do not 27).						
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ns, with regard to the approval	of this application, to the extent required by FIFRA.						
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II-In response. In addition, if the ta in the Agency's files that (1) ents in this product; and (2) is a	sponse is supported by all data submitted or cited in e cite-all option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted hit the initial registration of a product of identical or						
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mitter to use the study in supplic literature; (e) I have notified tions 3(c)(1)(F) and/or 3(c)(2)(	exclusive use study, either: (a) I am the original data wort of this application; (c) all periods of eligibility for in writing the company that submitted the study and B) of FIFRA; and (ii) to commence negotiations to						
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.							
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.							
Date	Typed or Printed Name and Title						
February 20, 2003	Dennis P. Ward, Regulatory Affairs Manager						
	Respect to Citation of 2005 (202) 383-2866  Bb1 and the genetic material orm  CFR Part 158:  Id EPA-registered product label in Statement (EPA Form 8570-2 with this form a list of companie the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the approval of the selective means, with required to the application, if the selective means, with required to the application or reregistration if the application sough the selection of the study.  Or reregistration or reregistration, at study.  Or reregistration that is not an electronic of the study in supplications 3(c)(1)(F) and/or 3(c)(2)(for the use of the study.  The selective means to the study in supplication of the study in supplications 3(c)(1)(F) and/or 3(c)(2)(for the use of the study.  The selective means to the study in supplication of the study.  The selective means to the study in supplication of the study.  The selective means to the study in supplication of the study.  The selective means to the selective means						

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TO THI DISCOULD THE TRADITIONS	in, DC 20460. Do not send the form to this address.	ATA MATRIX		<del></del>	<del></del>	
Date: February 20, 2003				EPA Reg. No./	File Symbol: 524-L	El Page I of 14
Applicant's/Registrant's Name (				2 - 1 - 1 - 0	E MON 961	-
	3th Street, N.W., Suite 660, Washington, D.C. 2000.	<del></del>	· (		rn Event MON 863	3
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	·	Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrater of a Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanio Com	pany	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300.	455382-09	Monsanto Com	pany	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Mittanck and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152.	454240-02	Monsanto Com	pany	<u>own</u>	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Hotteschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Hear Treatment, MSL-17223.	454240-07	Monsanto Company		OWN	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NITII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Com	pany	OWN	Dated May 21, 2001
Signature N. Wan	-112		Name and Title Dennis P. Ward, Ph Regulatory Affairs I	.D.   I	Date February 20, 2003	

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Date: February 20, 2003				EPA Reg. No	/File Symbol: 524-LEI	Page 2 of 14
Applicant's/Registrant's Name &		-	•		F . MON 063	
	Street, N.W., Suite 660, Washington, D.C. 2000		- (	·	orn Event MON 863	<del></del>
<del></del>	giensis Cry3Bb1 and the genetic material necessar		<del></del>	<del></del>	<del></del>	
Guideline Relerence Number	Guideline Study Name Administrative Materials in Support of the Registration of	MRID Number	Submitter	· · · · · · · · · · · · · · · · · · ·	Status	Note
151-26 885.2100	Bacillus thuringiensis Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Com; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, parts 1999.	451568-00	Mansanto Com	pany	own	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for Bacillus thuringiensis Cryl, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active	PP 7F4888	Monsanto Com	рапу	own .	Dated June 24, 1997
151-26 885.2100	Pilacinski, W. P. and M. W. Taylor (1999).  Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bacillus thuringiensis.  Com Rootworm Control Protein, as Produced in the Corn (Zea mays, L.), and the Amendment to the Previous.  Paguers for Expression from the Paguers of a	449043-00	Mansanto Com	прапу	OWN	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Com Event MON 863. MSL-17137.	454240-10	Monsanto Com	.pan y	own	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. ASS, 17154.	454240-11	Mousanto Com		OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs		Date February 20, 2003	

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Date: February 20, 2003			. EPA Reg	, No./File Symbol: 524-LE	I Page 3 of 14
Applicant's/Registrant's Name &		_			
	th Street, N.W., Suite 660, Washington, D.C. 2000		Product:		
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material necessar	ry for its productio	n (vector ZMIR13L) in event M	ON 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by E. coli Fermentation and Corn Event MON 863. MSL-17274.	455382-01	Monsanto Company	OWN	Dated November 5, 200
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Com Grain.	453731-01	Мопзапіо Сопрапу	OWN	Dated April 7, 2001
151-27 885.2400	Samples will be submitted as part of the independent laboratory method validation work that is ongoing.				
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Triats. MSL-171811.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
152-30 885.3050	Asiwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	454240-09	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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TO THE SHOOK, G. TY., TY ASTRINGTO	n, DC 20460. Do not send the form to this address.	ATA MATRIX				
Date: February 20, 2003				EPA Reg. N	lo./File Symbol: 524-LEI	Page 4 of 14
Applicant's/Registrant's Name & Monsanto Company, 600 L3	& Address: 5 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	15		Product: (	Corn Event MON 863	
	igiensis Cry3Bb1 and the genetic material necessar		n (vector ZMIR13L) ii	<del></del>	<del></del>	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-02	Monsanto Com	рапу	OWN	Dated November 5, 2001
152-30   885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001).  Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1  Protein Purified from Corn Event MON 863 and  Cry3Bb1 Protein Purified from E. coli. MSL-17292. A  pathogenicity determination is not applicable since	455382-03	Monsanto Com		OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the in vitro Digestibility of Cry3bBb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-02	Monsanto Com	pany	own	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little apportunity for dermal or ocular contact.					 
152-32 885,3150	Not applicable since Cry3ibl is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.					
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs		Date February 20, 2003	

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	n, DC 20460. Do not send the form to this address.	ATA MATRIX				
Date: February 20, 2003		· <del>-</del>		EPA Reg. N	lo./File Symbol: 524-LE	I Page 5 of 14
Applicant's/Registrant's Name &		_				
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	giensis Cry3Bb1 and the genetic material necessar	•	T			<del></del>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.			. "	İ	
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140.	454240-08	Monsanto Com	, pany	OWN	Dated May 21, 2001
152.36 152-37 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to Br crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.					
152-39 885.3500	Not applicable since Cry3libl is not a living organism.					
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999).  Bacillus thuringiensis Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite.  MSL-16161. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-15	Monsanto Com	pany	OWN	Dated August 19, 1999
Signature		·	Name and Title Dennis P. Ward, Ph Regulatory Affairs I	.D.	Date February 20, 2003	

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	D/	ATA MATRIX			
Date: February 20, 2003			. EPA	Reg. No./File Symbol: 524-LE	Page 6 of 14
Applicant's/Registrant's Name &		<del></del>		·	
Monsanto Company, 600 13	3th Street, N.W., Suite 660, Washington, D.C. 2000:	5	Prod	uct: Corn Event MON 863	
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material necessar	y for its production	n (vector ZMIR13L) in ever	nt MON 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	- Submitter	Status	Note
154-17	[				
885.4100	A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	····			
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-19 885.4200	Li, M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-19	Monsanto Company	own	Dated August 19, 1999
154.19 885.2600	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383.	455382-00	Monsanto Company	OWN	Dated November 5, 200
154-20 885.4240	Drottar, K.R. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living expaniem.	449043-18	Monsanto Company	_ own	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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40 M Gradi, C.W., Washing	ton, DC 20460. Do not send the form to this address.	ATA MATRIX	······································		<del></del>
	13th Street, N.W., Suite 660, Washington, D.C. 2000	<del></del>		EPA Reg. No./File Symbol: 524-I	
· · · · · · · · · · · · · · · · · · ·	ringiensis Cry3Bb1 and the genetic material necessar	<del></del>			<del></del>
Guideline Reference Number 154-21 885.4280	Results of acute toxicity tests with Daphnia and catfish did not produce any evidence of adverse effects. Testing with estuarine and marine species is not warranted because of very low to no putential for exposure to the Cry3 protein from field com. A pathogenicity	MRID Number	Submitter	Stalus	Note
	determination is not applicable since cry3Bb1 is not a living organism.				
154-22 885.4300	Cry3Bb1 is an insect toxin and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weedy wild relatives is virtually nonexistent.				
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (Hippodamia convergens). MSL-16166. A pathogenicity determination is not applicable since Cry38b1 is not a living organism.	449043-14	Mensanto Compa	Iny OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999).  Bacillus thuringiensis Protein [1231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate.  MSL-16162. A pathogenicity determination is not applicable since Cry3Bb] is not a living organism.	449043-16	Monsanto Compa	iny OWN	Dated August 19, 1999
Signature	9.07) Electronic and Bases versions available. Submit only		Name and Title Dennis P. Ward, Ph.E Regulatory Affairs M	gr	plornal Hea Cany

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Date: February 20, 2003 Applicant's/Registrant's Name	a & Address:		· · · · · · · · · · · · · · · · · · ·	EPA Reg. No	/File Symbol: 524-LEI	Page 8 of 14
	13th Street, N.W., Suite 660, Washington, D.C. 2000	5		Product: Co	orn Event MON 863	
Ingredient Bacillus thui	ringiensis Cry3Bb1 and the genetic material necessar	y for its production	n (vector ZMIR13L) in	event MON	863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the Bacillus thuringiensis Protein 11098 to Collembola (Folsomia candida). MSL-15988. A pathogenicity determination is not applicable since Cry38b1 is not a living organism.	449043-17	Monsanto Comp	ану	OWN	Dated August 19, 1999
154-23 885.4340	Patiner, S.J. and H.O. Krueger (†999). Bacillus thuringiensis Protein 11231: A Dietary Study with Green Lacewing Larvae (Chrysoperla carnea). MSL-16165. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12	Monsante Comp	any	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with the Parasitic Hymenoptera (Nasonia vitripennis). MSL-1616. A pathogenicity determination is not applicable since Cry3Bb1 is not a fiving organism.	449043-13	Monsanto Comp	pany	own	Dated August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgettic Corn Events on Nontarget Organisms: Preliminary Report. A pathogenicity determination is not applicable since Cry3Bbt is not a living organism.	453484-02	Monsanto Comp	nany	OWN	Dated February 20, 2001
154-23 885.4340	Duan, J.J., G. Head, M. McKee and T.E. Nickson (2001).  Dictary Effects of Transgenic Bacillus thuringiensis (Bt)  Com Pollen Expressing a Variant of Cry3Bb1 Protein on  Adults of the Ladybird Beetle, Coleomegilla maculata.  MSL-16936. A pathogenicity determination is not	453613-01	Monsanto Comi	nany	own	Dated March 20, 2001
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	D.	Date February 20, 2003	

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	D	ATA MATRIX				
Date: February 20, 2003				EPA Reg. N	lo./File Symbol: 524-LE	Page 9 of 14
	3th Street, N.W., Suite 660, Washington, D.C. 2000.			<del></del>	Corn Event MON 863	
Ingredient Bacillus thuring	igiensis Cry3Bb1 and the genetic material necessar	y for its production	on (vector ZMIR13L) i	n event MOI	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001).  Dietary Effects of Transgenie BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, Hippodamia convergens. MSL-17171. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-02	Monsanto Com	pany	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Com Routworm Insect-Protected Com on Non-Target Organisms. MSL-17179. A pathogenicity determination is not applicable since	455382-06	Monsanto Company		OWN	Dated November 5, 2001
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic bacillus thuringiensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Latvae of the Ladybird Reetle. Coleonegilla maculata. MSL-16907. A pathogenicity determination is not applicably ging Cry3Bb1 is not a living propagation.	455382-04	Monsanto Coin		OWN	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (Danus plexippus) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since	455382-05	Monsanto Com	рапу	OWN	Dated November 5, 2001
154-23 885.4340	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein in vitro. C3NTO. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07_	Monsanto Com	pany	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I		Date February 20, 2003	

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	D.	ATA MATRIX				
Date: February 20, 2003				EPA Reg. No	o./File Symbol: 524-LEI	Page 10 of 14
Applicant's/Registrant's Name &	Address: <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000				Corn Event MON 863	<del></del>
	giensis Cry3Bb1 and the genetic material necessar		(vector 2MIR I3I ) is		<del></del>	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	· i	Status	Note
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154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-03	Моляапто Сот	pany	OWN	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	456530-03	Monsanto Company		OWN _	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials.		Monsanto Com	ipany	own	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Con	ipany	OWN	Dated September 10, 2002
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified Bacillus thuringiensis Protein 11231 on Honey Bee Larvae. MSL-16168. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-10	Monsanto Coir	npany	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Pl Regulatory Affairs		Date February 20, 2003	

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	D.	ATA MATRIX				
Date: February 20, 2003				EPA Reg. N	a./File Symbol: 524-LE	Page 11 of 14
	3th Street, N.W., Suite 660, Washington, D.C. 2000			Product: C	Corn Event MON 863	·····
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material necessar	y for its productio	n (vector ZMIR13L) ir	event MON	V 863 corn	<b>*</b> • • • • • • • • • • • • • • • • • • •
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dictary Effect(s) of Purified Bacillus thuringieusis Protein 11231 on Adult Honey Bees (Apis mellifera L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Comp	ээпу	own	, Dated August 19, 1999
885.5200	Martin, J.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the B.J. Protein 11098 as a Component of Insect Protected Corn. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Com	pany	own	Dated June 20, 2000
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected Corn Event MON 863. MSL-17102.		Monsanto Comp	าลกง	own	Dated September 10, 2002
77	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bacillus thuringiensis Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors 73419.131, 73419.131, and 73419.141.)	450297-01	Monsanto Comp	nany	own	Dated January 13, 2000
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Conij	nany	OWN	Dated February 20, 2001
Signature	O7) Chatasia and Bass upplicate specifically		Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	i	Date February 20, 2003	

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Date: February 20, 2003			EPA Re	g. No./File Symbol: 524-LE	EI Page 12 of 14
Applicant's/Registrant's Name				V	<del>-</del>
Monsanto Company, 600 13	3th Street, N.W., Suite 660, Washington, D.C. 2000	5	Products	Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material necessar		on (vector ZMIR13L) in event N	40N 863 corn	
Guideline Reference Number	Guideline Study Name	MAID Number	Submitter	Status	Note
	Pilcher, C.D., I.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Hybrids as Determined in Year 2000 Field Trials.	453484-03	Monsanto Company	OWN	Dated February 20, 2001
	Pilcher, C.D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials.	453613-03	Monsanto Company	OWN	Dated March 20, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	454240-00	Monsanto Company	OWN	Dated May 21, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Com Rootworm Protected Com (Vector ZMIR13L); EPA File Symbol 524-LEI	455382-00	Monsanto Company	OWN	Dated November 5, 2001
	Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (Diabrotica barberi), Southern Corn Rootworm (D. undecimpunctata howardi), and Western Corn Rootworm (D. undecimpunctata howardi), and Western Corn Rootworm (D. undecimpunctata howardi), and Western Corn Rootworm (D. undecimpunctata howardi).	455382-08	Monsanto Company	OWN	Dated November 5, 2001
Signature	_	·	Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Date: February 20, 2003			,	EPA Reg. (	No./File Symbol: 524-LEI	Page 13 of 1
Applicant's/Registrant's Name						
	3th Street, N.W., Suite 660, Washington, D.C. 2000	<del></del>			Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material necessar	/———-	<del></del>			
Guideline Reference Number	Guideline Study Name	MRID Number	. Submitter		Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556.	455770-01	Monsanio Com	pany	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766.	456530-01	Monsanto Com	pany	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Com Event MON 863. MSL-17782.	456530-02	Monsanto Com	pany	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield Rootworm. MSL-17993.	45Ĝ923-01	Monsanto Com	рапу	OWN	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotransferase II as a Plant Pesticide Formulation Inert Ingredient. 93:132E	430547-00	Monsanto Com	pany	OWN	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I		Date February 20, 2003	

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Date: February 20, 2003	· · · · · · · · · · · · · · · · · · ·		·	EPA Reg. No.	/File Symbol: 524-LEI	Page 14 of 14
Applicant's/Registrant's Name & Monsanto Company (600-13)	. Address: <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000;	5		Brodusti Co	orn Event MON 863	
	giensis Cry3Bb1 and the genetic material necessar		r (vector ZMIR I 31.) in	· · · · · · · · · · · · · · · · · · ·		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTII) in Albino Mice. ML-91-409. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430547-01	Monsanto Com	рапу	оwи	Dated November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>In vitro</i> Mammalian Digestion Models. IRC-91-ANA-06. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430933-02	Monsanto Com	рапу	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	Monsanto Com	pany	PL	Dated November 23, 1993
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Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs		Date February 20, 2003	<del>*************************************</del>

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Date: February 20, 2003			. [6	PA Reg. No./File Symbol: 524-I	Ef Page 1 of 14
Applicant's/Registrant's Name	e & Address: 13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	05		Product: Corn Event MON 863	
	ingiensis Cry3Bb1 and the genetic material necessa		vector ZMIR13L) in e	vent MON 863 corn	
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Date: February 20, 2003 Applicant's/Registrant's Name & Address: Monsanto Company, 600-13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20005					EPA Reg. No./File Symbol: 524-LEI P		
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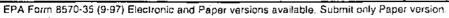
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·	D.	ATA MATRIX				
Date: February 20, 2003	•			EPA Reg. No./File Symbol: 524-L	EI Page 3 of 14	
Applicant's/Registrant's Name & Address:				,		
Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005				Product: Corn Event MON 863		
Ingredient Bacillus thurin	igiensis Cry3Bb1 and the genetic material necessur	y for its production	n (vector ZMIR13L) in	event MON 863 corn		
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DATA MATRIX			
Date: February 20, 2003 Applicant's/Registrant's Name & Address:	EPA Reg. No./File Symbol: 524-L	EI Page 4 of 14	
Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005  Ingredient Bacillus thuringiensis Cry38b1 and the genetic material necessary for its production	7MID 131 )	Product: Corn Event MON 863	<del> </del>
Ingredient Bacillus thuringiensis Cry38b1 and the genetic material necessary for its productio Guideline Reference Number Guideline Study Name MRID Number	n (vector ZIVITRT3L) If Submitter	Status	Note
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Signature	Name and Title Dennis P. Ward, Ph Regulatory Affairs N		

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Applicant's/Registrant's Name & Address:		<del></del>			
Monsanto Company, 600 13th Street, N.W., Suite 660,			<del>~~~~~~~~</del>	Product: Corn Event MON 863	
Ingredient Bacillus thuringiensis Cry3Bb1 and the ge	enetic material necessar	y for its production	(vector ZMIR13L) in e	event MON 863 corn	
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Date: February 20, 2003				EPA Reg. No./File Symbol: 524-L	El Page 14 of 14
Applicant's/Registrant's Name &	Address:	_			
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	giensis Cry3Bb1 and the genetic material necessar				<del></del>
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#### CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

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{CBI Cross Reference Number 1}

Page 34 of 45

#### PRODUCT LABEL

Five copies of the proposed label for 'Com Event MON 863: Rootworm Protected Com' are attached. This label supersedes the label previously submitted to EPA, dated February 11, 2003.

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#### Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: YieldGard Rootworm®: Rootworm Protection]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

#### **Active Ingredient:**

#### Other Ingredients:

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

#### **CAUTION**

® YieldGard Rootworm is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.



#### **Insect Resistance Management**

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

#### Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the B.t. protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (Diabrotica virgifera virgifera) Northern corn rootworm (Diabrotica barberi) Mexican corn rootworm (Diabrotica virgifera zeae)

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# CONFIDENTIAL ATTACHMENT



Amendment of the Application to Register a Bacillus thuringiensis
Cry3Bb1 Protein and the Genetic Material Necessary for its
Production (Vector ZMIR13L) in Event MON 863 Corn;
EPA File Symbol 524-LEI

#### CONFIDENTIAL ATTACHMENT

#### **AUTHOR**

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

#### DATE

February 20, 2003

#### SUBMITTING REGISTRANT

Monsanto Company 600 13<sup>th</sup> Street N.W. Suite 660 Washington, DC 20005

#### MONSANTO REFERENCE No.

00-CR-032E-17

124

#### CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

Pages	Reason for Deletion	FIFRA Reference
37 & 38	Discloses commercial information	§10(d)(1)(A), (B) or (C)

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Volume 4 of 4
Page is not included in this copy.
Pages \ through \ are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product inert impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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Date: February 20, 2003				EPA Reg. No./File	Symbol: 524-LE	I Page 1 of 16
Applicant's/Registrant's Name (				<u>-</u>		<u> </u>
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Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	·	Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrater of a Bacillus thuringiensis Cry3Bbt Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanto Comp	nany	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300.	455382-09	Monsanto Comp	any	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Mittanck and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152.	454240-02	Monsanto Corp	pany	own_	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment, MSL-17223.	454240-07	Monsuata Com	nany	own	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Com Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Com		OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	Date D. Febr	uary 20, 2003	

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Date: February 20, 2003				EPA Rog. N	lo/File Symbol: 524-LEI	Page 2 of 16
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	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000			4. <del></del>	Corn Event MON 863	
Ingredient Bacillus thurin	igiensis Cry3Bb1 and the genetic material necessar	y for its production	n (vector ZMIR13L) i	n event MO	N 863 com	
Guidelina Reference Number	Guldeline Study Name	MRID Number	Submitter		Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of Bacillus thuringiensis Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance,	451568-00	- Monsanto Com	ipany	OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for Bacillus thuringiensis Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active	) PP 7F4888	Monsanto Con	прапу	OWN	Dated June 24, 1997
151-26 885.2100	Pilacinski, W. P. and M. W. Taylor (1999).  Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bacillus thuringiensis.  Com Rootworm Control Protein, as Produced in the Corn (Zea mays, L.), and the Amendment to the Previous.  Pennet for Expression from the Paguinesses, of	449043-00	Mgnsanio Con	эрапу	OWN	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry38b) Protein Produced in Corn Event MON 863. MSL-17137.	454240-10	Monsanto Cor	npany	OWN	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hiteman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863  Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric  Tacheiman A421, 13154	454240-11	Monsanio Cor		OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, P Regulatory Affairs	h.D.	Date February 20, 2003	

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Date: February 20, 2003				EPA Reg. No./File Symbol: 524-	LEI Page 3 of 16
Applicant's/Registrant's Name &	Address:	<u> </u>			
	th Street, N.W., Suite 660, Washington, D.C. 2000			Product: Corn Event MON 86	53
	giensis Cry3Bb1 and the genetic material necessar		<del>,</del>	<del> </del>	<del></del>
Guideline Relarance Number	Guideline Study Name	MRID Number _	Submitter	Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by E. coli Fermentation and Corn Event MON 863. MSL-17274.	455382-01	. Молзалто Сог	pany OWN	Dated November 5, 2001
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases, MSL-17140.	454240-08	Monsanto Com	pany OWN	Daled May 21, 2001
885.2250	Not applicable since feed residues of Cry3Bbi-protein are not of toxicological concern and there is no requirement for a tolerance in animal tissues.				
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain.	453731-01	Monsanto Com	ралу ОWN	Dated April 7, 2001
885.2350	Not applicable since there is no need for a Cfy3B61 tolerance in noimal disses.				
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs	1	3

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Date: February 20, 2003				EPA Reg. No./File	Symbol: 524-LEI	Page 4 of 16
Applicant's/Registrant's Name &				××		··
Monsanto Company, 600 13	3th Street, N.W., Suite 660, Washington, D.C. 2000	)5		Product: Com E	Event MON 863	
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material necessa	ry for its productio	n (vector ZMIR13L) in	event MON 863	corn	
Guldeline Reference Number	Guldelina Study Name	MRID Number	Submitter		Status	Nate
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151-27 - <del>885</del> :2400	Smales				ſ	
	independent laboratory method validation work that is	**************************************		والمراجعة المساء والمطابق والمسادرة والمسادرة والمسادرة	پوپ، يەستوا	
	ongoing.	<del> </del>	<del> </del>	<del></del>		· · · · · · · · · · · · · · · · · · ·
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTII Protein Levels in Sample					5.4
	Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Comp	залу .	own	Dated May 21, 2001
885 <del>/2550</del>	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.					
885.2600	Not applicable since there are not expected to be any water residues of toxicological concern.					
885.2600 154-19	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383.	455382-00	Monsanio Coin	pany	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs !		te oruary 20, 2003	

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Dato: February 20, 2003	·	·	•	EPA Reg. No	o./File Symbol: 524-LE	I Page 5 of 16
Applicant's/Registrant's Name 8	Address:		<del></del>			
	Street, N.W., Suite 660, Washington, D.C. 2000				com Event MON 863	
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material necessar	y for its productio	n (vector ZMIR13L) in	event MON	1 863 com	
Guideline Reference Number	Quideline Study Name	MRID Number	. Submitter		Status	Note
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	454240-09	Молзаліо Сого	рапу	OWN	Dated May 21, 2001
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with E. coli Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-02	Monsanto Com	ралу	OWN	Dated November 5, 200
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001).  Assessment of the in vitro Digestibility of Cry3Bb1  Protein Purified from Corn Event MON 863 and  Cry3Bb1 Protein Purified from E. coli. MSL-17292. A  pathogenicity determination is not applicable since	455382-03	Mansanto Com		OWN	Dated November 5, 200
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the in vitro Digestibility of Cty3bBb1.11098(Q349R) Protein in Simulated Intestinal Pluid. MSL-17530. A pathogenicity determination is not applicable since Cty3Bb1 is not a living organism.	455770-02	Monsanio Com	ралу	OWN	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry38b1 is a plant-incorporated active ingredient, is present at low levels, and there is little apportunity for dermal or ocular contact.			:		
Signature		• .	Name and Title Dennis P. Ward, Ph Regulatory Affairs I		Date February 20, 2003	

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Date: February 20, 2003				EPA Reg. N	o./File Symbol: 524-LEI	Page 6 of 16
Applicant's/Registrant's Name (	s Address: 3 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	5		Product: 0	Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material necessar		(vector ZMIR13L) is	<del></del>		<del> </del>
Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter		Status	Note
152-32 885.3150	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.					
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.			,		
152-37 (J) 34 J4 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to Bt crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.					
152-39 885.3500	Not applicable since Cry3Bb1 is not a virus.					
152-42 885.3600	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in tom grain, and is rapidly degraded in the digestive tracks of mammals.					
Signature			Name and Title Dennis P. Ward, Pl Regulatory Affairs		Date February 20, 2003	

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Date: February 20, 2003			-	EPA Reg. No.	/File Symbol: 524-LE	I Page 7 of 16
Applicant's/Registrant's Name &		<del></del>	<del>, , , , , , , , , , , , , , , , , , , </del>	(	<u> </u>	<del></del>
	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	<del></del>	<u> </u>	<del></del>	rn Event MON 863	
Ingredient Bacillus thurin	igiensis Cry3Bb1 and the genetic material necessa	ry for its production	(vector ZMIR13L) i	n event MON	863 corn	<b></b>
Guideline Reference Number	Guldeline Study Name	MRID Number	. Submitter		Status	Note
885.3650	Not applicable since Cry3Bo1 in glant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of mammals.					
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999).  Bacillus thuringiensis Protein 1123! in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite.  MSL-16161. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-15	Monsanto Com	пралу	own	Dated August 19, 199
154-17 885.4100	Not applicable since CW3Hbt A a plant-incorporated at the local gradulers is little applicable; to avoid inhabition exposule. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.			-		
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				•	
_	Li, M.H. and E.H. Robinson (1999). Evaluation of Insect	}		1		

449043-19

Monsanto Company

Name and Title

Dennis P. Ward, Ph.D.

Regulatory Affairs Mgr.

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living organism.

Protected Com Lines MON 853 and MON 859 as a Feed

Ingredient for Catfish. MSL-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a

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February 20, 2003

Date



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Signature

Dated

August 19, 1999

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Date: February 20, 2003				EPA Reg. N	No./File Symbol: 524-LEI	Page 8 of 16
Applicants/Registrant's Name (	& Address:	<del></del>			<u> </u>	
Monsanto Company, 600 13	3th Street, N.W., Suite 660, Washington, D.C. 2000	5		Product:	Corn Event MON 863	
Ingredient Bacillus thurin	igiensis Cry3Bb1 and the genetic material necessar	y for its production	n (vector ZMIR13L) is	event MO	N 863 com	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-20 885.4240	Drottar, K.R. and H.O. Krueger (1999). Bacillus shuringiensis Protein 11098 in Com Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a	449043-18	Monsanto Com	banà.	OWN	Dated August 19, 1999
154-21 885.4280	Com is not typically grown in close proximity to estuarine or marine environments. Polten drift into these environments would not result in water residues of toxicological concern. A pathogenicity determination is not applicable since Cry3Bbl is not a living organism.			-		
154-22 885.4300	Not applicable since Cry3Bb1 is plant-incorporated and not 'applied' to crops.		;			
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringlensis Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (Hippodamia convergens). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-14	Monsanto Con	рапу	OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999).  Bacillus thuringiensis Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate.  MSL-16162. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	_449043-16	Monsanto Con	pany	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Pl Regulatory Affairs		Date February 20, 2003	

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Date: February 20, 2003		·		EPA Reg. No./Fi	lle Symbol: 524-LEI	Page 9 of 16
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	3th Street, N.W., Suite 660, Washington, D.C. 2000	<del></del>	<u>,</u>		Event MON 863	
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material necessar	ry for its productio	n (vector ZMIR13L) in	i event MON 86	3 corn	<del>, _</del>
Guideline Reference Number	Guidoline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the Bacillus thuringiensis Protein 11098 to Collembola (Folsomia candida). MSL 15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-17	Monsanto Com	pany	own	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with Green Lacewing Larvac (Chrysoperla carnea). MSL-16165. A puthogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12	Monsanto Com	pany	own	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with the Parasitic Hymenoptera (Nasania vitripennis). MSL-1616. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-13_	Monsanto Com	pany _	own	Daied August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453484-02	Monsanto Com	nany	own	Dated February 20, 2001
154-23 885.4340	Duan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic Bacillus thuringiensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, Coleomegilla maculata. MSL-16936. A pathogenicity determination is not	453613-01	Monsanio Com	pany	OWN	Dated March 20, 2001
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	.D. Fe	ate ebruary 20, 2003	

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Date: February 20, 200	13		·	EPA Reg. No./File Symbol: 524-I	EI Page 10 of 16
Applicant's/Registrant's No Monsanto Company, 60	ame & Address: 00-13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	5		Product: Corn Event MON 86	3
Ingredient Bacillus t	huringiensis Cry3Bb1 and the genetic material necessar	y for its production	(vector ZMIR13L) in	event MON 863 corn	
<b>Guideline Reference Num</b>		MAID Number	Submitter	Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dictary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, Hippodamia convergens. MSL-17171. A pathogenicity determination is not applicable since Cry3Bb1 is not a	453613-02	Moosanto Comp	ллу OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.P. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179. A pathogenicity determination is not applicable since	455382-06	Monsanto Company OWN  Monsanto Company OWN		Dated November 5, 2001
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001).  Dietary Effects of Transgenic Bacillus thuringiensis (Bt)  Corn Pollen Expressing a Variant of Cry3Bb1 Protein on  Larvae of the Ladybird Beetle, Coleonegilla maculata.  MSL-16907. A pathogenicity determination is not	455382-04	Monsunto Comp	any OWN	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (Danus plexippus) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since	455382-05	Monsanio Comp	any OWN	Dated November 5, 200
154-23 885.4340	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry38b Protein in vitro. C3NTO. A pathogenicity determination is not applicable since Cry38b1 is not a living organism.	455382-07	Monsanto Comp	ony OWN	Dated November 5, 200
Signature	·	<del></del>	Name and Title Dennis P. Ward, Ph. Regulatory Affairs M	, · · · · · · · · · · · · · · · · · · ·	3

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Date: February 20, 2003 EPA Reg. No./File Symbol: 524-LEI Page 11 of 16 Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005 Product: Corn Event MON 863

Bacillus thuringiensis Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Duan, J.J., M. J. McKee; G. Head and C.R. Brown 154-23 (2002). Endangered Species Impact Assessment for 885,4340 Cry3Bb1 Protein in Transgenic Com Event MON 863. MSL-17614. A pathogenicity determination is not Dated applicable since Cry3Hb1 is not a living organism. 455770-03 Monsanto Company OWN January 8, 2002 Head, G. (2002). Research on the Effects of Com-154-23 Rootworm Protected Transgenic Corn Events on 885.4340 Nontarget Organisms: Preliminary Results. A pathogenicity determination is not applicable since Dated Cry3Bb1 is not a living organism. 456530-03 OWN April 9, 2002 Monsanto Company Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pitcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). 154-23 Ecological Assessment of Nontarget Organisms in the 885,4340 Dated Plots of Corn Rootworm Insect Protected Corn Hybrid September 10, Containing MON 863 Event: 2000 - 2001 Field Trials. Monsanto Company OWN 2002 Dunn = 1451 17571 Appelananiain determination in Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). 154-23 Evaluation of a Cry3Bb1 Protein Variant in an Acute 885,4340 Toxicity Study with the Earthworm in an Artificial Soil Dated Substrate, MSL-18137. A pathogenicity determination September 10, is not applicable since Cry38b1 is not a living organism. Monsanto Company OWN 2002 154-24 Maggi, V.L. (1999). Evaluation of the Dictary Effects of 885.4380 Purified Bacillus thuringiensis Protein 11231 on Honey Bee Larvae, MSL-16168. A pathogenicity determination Dated is not applicable since Cry38b1 is not a living organism. 449043-10 Monsanto Company OWN August 19, 1999 Signature Name and Title Date Dennis P. Ward, Ph.D. February 20, 2003 Regulatory Affairs Mgr.

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Monsanto Company

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Farm Approved OMB No. 2070-0060

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DATA MATRIX

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Date: February 20, 2003			· · · · · · · · · · · · · · · · · · ·	EPA Reg. No./File Symbol: 524-LEI		EI Page 12 of 16	
Applicant's/Registrant's Name & Address:  Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005  Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L)				Product: Corn Event MON 863			
Guideline Reference Number	Guideline Study Name	MRID Number	- Submitter		Status	Note	
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified Bacillus thuringlensis Protein 11231 on Adult Honey Bees (Apis mellifera L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Company		OWN	Dated August 19, 1999	
154-26 885.4600	Not applicable; no triggers hit for tier III testing. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.			· .			
154-28 885.4700	Not applicable; no triggers hit for tier III testing. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.						
154-29 885.4750	Not applicable since com is not grown in an aqueous environment. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.						
885.5200	Martin, I.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the B.t. Protein 11098 as a Component of Insect Protected Com. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	, Monsanio Cor	прэпу	OWN	Dated June 20, 2000	
Signature			Name and Title Dennis P. Ward, P Regulatory Affairs		Date February 20, 2003		

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	D	ATA MATRIX			<del> </del>
Date: February 20, 2003		·	EPA R	eg. No./File Symbol: 524-LE	Page 13 of 1
Applicant's/Registrant's Name &	Address:		)		
	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000		<del></del>	: Corn Event MON 863	
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material necessar	ry for its production	n (vector ZMIR13L) in event l	MON 863 com	<del></del>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the Bucillus thuringiensis Cry3Bb1 Variant Protein Produced in Com Rootworm Protected Com Event MON 863. MSL-17102.		Monsanto Coropany	О₩И	Daled September 10, 2002
885.5300	Not applicable since com is not grown in an aqueous environment.				
885.5400	Not applicable since com is not grown in an aqueous environment.				
THE PROPERTY OF THE PROPERTY O	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bocillus thuringiensis Cry3Bb Protein, and the Genetic Material Necessary for its Production in Com (Vectors			OWN	Dated
<del></del>	73410131 73510331 and 734103413	450297-01	Monsanto Company	- Uwn	January 13, 200
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Com Rootworn Control Product.	453484-01	Monsanto Company	OWN	Dated
Signature		<del></del>	Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX Date: February 20, 2003 EPA Rog. No./File Symbol: 524-LEI Page 14 of 16 Applicants/Rogistrant's Name & Address: Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005 Product: Corn Event MON 863 Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Pilcher, C.D., J.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Dated OWN February 20, 2001 Hybrids as Determined in Year 2000 Field Trials. 453484-03 Montanto Company Pilcher, C.D. (2001). Efficacy of MON 863 Against Com Rootworm and Comparison to Insecucide Dated Treatments - Results of Year 2000 Field Trials. Monsanto Company OWN March 20, 2001 453613-03 Administrative Materials in Support of the Application for Registration of Event MON 863: Com Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol Dated OWN May 21, 2001 524-LEI 454240-00 Monsanto Company Administrative Materials in Support of the Application for Registration of Event MON 863: Com Rootworm Protected Corn (Vector ZMIR13L): EPA File Symbol Dated November 5, 2001 455382-00 Monsanto Company OWN 524-LEI Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (Diabrotica barberi), Southern Com-Dated Rootworm (D. undecimpunctata howardi), and Western 455382-08 Monsanto Company OWN November 5, 2001 Signature Name and Title Date Dennis P. Ward, Ph.D February 20, 2003 Regulatory Affairs Mgr.

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Date: February 20, 2003				EPA Reg. No./File Symbol: 524-LEI   Page 15		
Applicant's/Registrant's Name (	Address:				· ·	
	3th Street, N.W., Suite 660, Washington, D.C. 2000		Product: Corn Event MON 863			
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material necessar	y for its productio	n (vector ZMIR13L) in	event MON 8	63 com	•
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556.	455770-01	Monsanto Comp	any	OWN	Dated January 8, 2002
·	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766.	456530-01	Monsanto Company OWN		OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Com Event MON 863. MSL-17782.	456530-02	Monsanto Comp	іалу	own	Dated April 9, 2002
<u></u>	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Com Rootworm Resistant Varietal Technology - Yield Rootworm. MSL-17993.	456923-01	Monsanto Comp	pany	own	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotrans ferase II as a Plant Pesticide Formulation Inert Ingredient, 93-132E	430547-00	Monsanto Comp	pany	OWN	Dated November 23, 1993
Signature		Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	D F	Date Sebruary 20, 2003	,	

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DATA MATRIX						
Date: February 20, 2003	EPA Reg. No./File Symbol: 524-LEI	Page 16 of 16				
Applicant's/Registrant's Name & Address:		<del></del>				
Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005	Product: Corn Event MON 863					

Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material necessar	y for its production	(vector ZMIR13L) in event MC	N 863 com	y
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTII) in Albino Mice. ML-91-409. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430547-01	Monsanto Company	OWN	Daled November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>In vitro</i> Mammalian Digestion Models. IRC-91-ANA-06. A pathogenicity determination is not applicable since Cry38b1 is not a living organism.	430933-02	Monsanto Company	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	PL · ¨		Dated November 23, 1993
,	_ , _ ,				
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 20, 2003	

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Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 Monsanto Company 700 Chesterfield Pkwy West Chesterfield, MO 63017 PHONE (314) 594-1000 FAX (636) 737-5943 http://www.monsanto.com

February 14, 2003

Janet L. Andersen, Ph.D. (7511C)
Director, Biopesticides and Pollution Prevention Division
Office of Pesticides Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subj: Monsanto acceptance of terms and conditions for registration of MON 863 Response to your letter of February 14, 2003

Dear Dr. Andersen:

Monsanto has carefully reviewed the contents of the Agency's MON 863 Cry3Bb1 Corn Preacceptance letter, dated February 14, 2003, and agrees to all terms and conditions set forth in this letter. In addition, we have submitted revised labeling that conforms to the refuge requirements as specified in said pre-acceptance letter.

As indicated, it is Monsanto's intention to submit within 60 days a petition to convert the Cry3Bb1 time-limited tolerance exemption to a nonexpiring tolerance exemption. At the same time we will also be submitting an application to extend the length of the registration.

Should you have any questions regarding our response please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

cc: Russell Schneider, Monsanto

144



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Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 Monsanto Company 700 Chesterfield Pkwy West Chesterfield, MO 63017 PHONE (314) 694-1000 FAX (636) 737-5943 http://www.monsanto.com

February 13, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863

EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing a revised data matrix, label and Confidential Statement of Formula for Corn Event MON 863.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the confidential attachment, Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincere**k**y,

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

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Mr. P. Hutton 2/11/2003 Page 2 of 49

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto

Please read instructions on	reverse before completin	g form.	Form A	pproved. OM	B No. 20	70-0060.	Approval E	xpires 2-28-95
<b>SEPA</b>	Environmer Was	United States Ital Protect Shington, DC 2	tion Agenc	у		Registr Amend Other		OPP Identifier Number
· · · · · · · · · · · · · · · · · · ·	Applica	tion for P	esticide – S	Section I	<u> </u>	·· <del>· · · · · · · · · · · · · · · · · ·</del>	<del></del>	<u> </u>
Company/Product Number     File Syr	mbol 524-LEI		2. EPA Produc	<del></del>	itton		3. Propos	sed Classification
Company/Product (Name)	nt MON 863		PM#	90			X №	ne Restricted
5. Name and Address of Applicant ( Monsanto Company 600 13 <sup>th</sup> St., N.W., Suite 660 Washington, DC 20005 Check if this is a new address		Soot	6. Expedited product is similar EPA Reg. No. Product Name	ar or identical	in comp	osition and	tabeling to	·
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Submission of revised data m	natrix, labeling and C	CSF		·		·		
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Material This Product Will Be F Child-Resistant Packaging     Yes*     No  * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per Container	Water Soluble Paragraphy Yes No  If "Yes" Package wgt.	No. per Container		Pape Of Oth	al stic ss ser	
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Label Container	on	4. Size(s) Retai	il Container			n Label	bel Direction	ns ying product
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1. Contact Point (Complete items dire	ectly below for identification			necessary, to	proces	s this appl	icatior)	·
Name Russell P. Sc		<del></del>	Regulatory Af	fairs Direc	tor	Tele	phoria No. (202) 3a	(Include Area Code) 33-2866
I certify that the statements I ha I acknowledge that any knowing both under applicable law.  2. Signature	ve made on this form and	ertification all attachments tement may be 3. Title	ounishable by fine	or imprisonn	nent or	'e.	į	5. Oate Application Received (Stamped)
<u> </u>			Regulatory A	ITAIRS Man	ager		۱ ا	
Typed Name     Dennis P. Ward	Tel. (636) 737-6631	<u> </u>	February 13,	2003	<del></del> -			147
EPA Form 8570-1 (Rev. 3-9	4) Previous editions are	obsolete.	White - EPA	File Copy (c	original)	Yellov	v - Applica	nt Copy

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WASHINGTON, D.C. 20460

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burden to Director, OPPE Information Management Division (2137), U.S. Do not send the completed form to this address.	Environmental Protection Age	ency, 401 M Street, S.W., Washington DC, 20460.
Certification with Re	espect to Citation of	Data
Applicant's/Registrant's Name, Address, and Telephone Number:	· <del></del>	EPA Registration Number / File Symbol:
Monsanto Company, 600 13th Street, N.W., Washington, DC 200	05 (202) 383-2866	524-LEI
Active ingredient(s) and/or representative test compound(s): B.t. Cry3Bb necessary for its production (vector ZMIR13L) in event MON 863 corn	_	Date: February 13, 2003
General Use Pattern(s) (list all those claimed for this product using 40 CF	FR Part 158:	Product Name:
Terrestrial field crop		Corn Event MON 863
NOTE: If your product is a 100% repackaging of another purchased to submit this form. You must submit the Formulator's Exemption 5		
I am responding to a Data-Call-in Notice, and have included with should be used for this purpose).	h this form a list of companies	sent offers of compensation (the Data Matrix form
Section I: METHOD OF DAT	A SUPPORT (Check of	one method only)
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Section II: GEN	ERAL OFFER TO PA	Y
(Required if using the cite-all method or when using the cite-all of hereby offer and agree to pay compensation, to other persons.)	·	-
Section III:	CERTIFICATION	
I certify that this application for registration, this form for reregist the application for registration, the form for registration, or the Data-Callmethod is indicated in Section 1, this application is supported by all data an identical or substantially similar product, one or more of the ingredient under the data requirements in effect on the date of approval of this application and uses.	in response. In addition, if the in the Agency's files that (1) o is in this product; and (2) is a	cite-all option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted
I certify that for each exclusive use study cited in support of this obtained the written permission of the original data submitter to cite that	registration or reregistration, t study.	hat I am the original data submitter or that I have
I certify that for each study cited in support of this registration or submitter; (b) I have obtained the permission of the original data submitter; (b) I have expired for the study; (d) the study is in the public have offered (i) to pay compensation to the extent required by section determine the amount and terms of compensation, if any, to be paid for the study is a support of the study in the paid for the study is a support of the study in the study in the study is supported by the study in the study in the study in the study is supported by the study in the study in the study in the study is supported by the study in the study in the study in the study in the study is supported by the study in the study in the study in the study is in the public by the study in the study in the study is in the study in the study in the study in the study is in the study in the study in the study in the study is in the study in the study in the study in the study in the study is in the study	itter to use the study in supp literature; (e) I have notified in ns 3(c)(1)(F) and/or 3(c)(2)(E	ort of this application; (c) all periods of eligibility for n writing the company that submitted the study and
I certify that in all instances where an offer of compensation is reaccordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available such evidence to the Agency upon request, I understand that the Agency conformity with FIFRA.	ble and will be submitted to the	ne Agency upon request. Should I fail to produce
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I certify that the statements I have made on this form and all knowingly false of misleading statement may be punishable by fine		
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knowingly false of misleading statement may be punishable by fine Signature	or imprisonment of both ur	der the applicable law.

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Washington, D.C. 20460

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Date: February 13, 2003		·		EPA Reg. No	./File Symbol: 524-	LEI Page I of 16
Applicant's/Registrant's Name						-
	3th Street, N.W., Suite 660, Washington, D.C. 2000.				orn Event MON 86	53
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material (vector Z	MIR13L) necessar	y for its production in	event MON	863 corn	<del></del>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrater of a <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Com Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanto Com	pany	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300; an unpublished study conducted by Monsanto Company.	455382-0 <del>9</del>	Monsanto Com	pany	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885,1100 885,1200 885,1300 885,2100	Cavato, T.A., E.C. Rigden, D.W. Mittanck and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152; an unpublished study conducted by Monsanto Company.	454240-02	Monsanto Com	bany	OWN	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001).  Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Cont Events MON 863 and MON 853 After Heat Treatment. MSL-17223; an appetitional study confusion by Moneous Company.	454240-07	Monsánto Com	pany	OWN	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500. 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTH Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811: an unpublished study company.	454240-01	Monsanto Com		OWN	Dated May 21, 2001
Signature		_	Name and Title Dennis P. Ward, Ph Regulatory Affairs I	.D.	Date February 13, 2003	3

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	D.	ATA MATRIX				
Date: February 13, 2003				EPA Reg. N	o./File Symbol: 524-LE	Page 2 of 16
Applicant's/Registrant's Name &			•		•	
	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000.				Corn Event MON 863	
Ingredient Bacillus thurin	giensis Cry3Bb1 and the genetic material (vector 2	ZMIR13L) necess	ary for its production i	n event MON	N 863 corn	
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of Bacillus thuringlensis Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Com; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, DRIESESS.	451568-00	   Monsanto Com	pany	.OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for Bacillus thuringiensis Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Incompletes	PP 7F4888	Monsanto Com	pany	OWN	Daled June 24, 1997
151-26 885.2100	Pilacinski, W. P. and M. W. Taylor (1999).  Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bacillus thuringiensis  Com Rootworm Control Protein, as Produced in the Com (Zea mays, L.), and the Amendment to the Previous  Rootset for Exampling from the Requirement of A.	449043-00	Monsanto Com	pany	own	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Corn Event MON 863. MSL-17137; an unpublished study conducted by Monsanto Company.	454240-10	Monsanto Com	pany	own	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric. Techniques. MSL 17154: on unpublished coulds.	454240-11	Monsanto Com	pany	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I		Date February 13, 2003	

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	D/	ATA MATRIX				
Date: February 13, 2003				EPA Reg. No.	/File Symbol: 524-LB	Page 3 of 16
Applicant's/Registrant's Name 8		<del></del> .	<del></del>	2.777.09.770.0		, <del></del>
Monsanto Company, 600 13	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000	5		Product: Co	orn Event MON 863	
	igiensis Cry3Bb1 and the genetic material (vector 2		ry for its production in	event MON	863 com	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by E. coli Fermentation and Com Event MON 863. MSL-17274; an unpublished study conducted by Monsanto	455382-01	Мопѕанто Сол	pany	OWN	Dated November 5, 200
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140; an unpublished study conducted	454240-08	Monsanto Com	pany	OWN	Dated May 21, 2001
153-4 885.2250	Not applicable since feed residues of Cry3Bb1 protein are not of toxicological concern and there is no requirement for a tolerance in animal tissues.					
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. An unpublished report prepared by Monsanto Company.	453731-01	Monsanto Com	pany	own	Dated April 7, 2001
151-25 885.2350	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.					
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I	.D.	Date February 13, 2003	

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Date: February 13, 2003				EPA Reg. No./File Symbol: 524-LB	I Page 4 of 16
Applicant's/Registrant's Name &					
Monsanto Company, 600 13	<sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 200	05		Product: Corn Event MON 863	
Ingredient Bacillus thurir	giensis Cry3Bb1 and the genetic material (vector	ZMIR13L) necess	ary for its production ir	n event MON 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-27 885.2400	Storage stability data will be submitted as part of the independent laboratory method validation work that is ongoing.				
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.t1098 and NPTII Protein Levels in Sample Tissue Collected from Com Event MON 863 Grown in 1999 Field Trials. MSL-17181I; an unpublished study conducted by Moncooky Company.	454240-01	Monsanto Comp	pany OWN	Dated May 21, 2001
153-4 885.2550	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.				
153-4 885.2600	Not applicable since there are not expected to be any vater residues of toxicological concent.				
153-4 885.2600	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383; an analysis conducted by Monsar to Company.	455382-00	Monsanto Comp	pany OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs M	, , ,	,

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	D	ATA MATRIX				
Date: February 13, 2003				EPA Reg. N	lo./File Symbol: 524-L	EI Page 5 of 16
Applicant's/Registrant's Name Monsanto Company, 600 1	3th Street, N.W., Suite 660, Washington, D.C. 2000			Product: (	Corn Event MON 863	
Ingredient Bacillus thuri	ngiensis Cry3Bb1 and the genetic material (vector i	ZMIR13L) necessa	ary for its production i	n event MOI	N 863 corn	
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter		Status	Note
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Com. MSL-17225; an unpublished analysis prepared by Monsanto Company.	454240-09	Monsanto Com	pany	OWN	Dated May 21, 2001
152-30 885,3050 885,4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with E. coli Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382; an unpublished study conducted for Monsanto Company.	455382-02	Monsanto Com	pany	OWN	Dated November 5, 2001
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001).  Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1  Protein Purified from Corn Event MON 863 and  Cry3Bb1 Protein Purified from <i>E. coti</i> . MSL-17292; an unpublished study conducted by Monsanto Company.	455382-03	Monsanto Com	ipany	OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3bBb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530; an unpublished study conducted by Monsanto Company	455770-02	Monsanto Corr	npany	OWN	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for dermal or ocular contact.					
Signatu.e			Name and Title Dennis P. Ward, Ph Regulatory Affairs		Date February 13, 2003	

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Monsanto Company

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	Diff, DC 20460. Do not send the form to this address.	NATA MATRIX				
Date: February 13, 2003 Applicant's/Registrant's Name	8 Address		· .	EPA Reg. f	No./File Symbol: 524-LEI	Page 6 of 16
Monsanto Company, 600 1	3th Street, N.W., Suite 660, Washington, D.C. 2000				Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material (vector		ary for its production in	event MO	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	, Submitter		Status	Note
152-32 885,3150	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure.					
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.					
152-37 152-38 885,3400	There are no documented reports of hypersensitivity reactions to Bt microbial formulations or proteins; McClintock et al., (1995) Pestic, Sci. 45:95-105.			٠.	PL_	
152-39 885.3500	Not applicable since Cry3Bb1 is not a virus.	1				
152-42 885.3600	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of manimals.			. ==,,==		
Signature	.97) Electropia and Paner versions available. Submit only		Name and Title Dennis P. Ward, Ph. Regulatory Affairs N		Date February 13, 2003	

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401 M Street, S.W., Washingto	n, DC 20460. Do not send the form to this address.	ATA MATRIX				
Date: February 13, 2003				EPA Reg. N	o./File Symbol: 524-LEI	Page 7 of 16
Applicant's/Registrant's Name &	k Address: <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000:	:		Deadwate (	Corn Event MON 863	
	giensis Cry3Bb1 and the genetic material (vector Z		ry for its production is			
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter		Status	Note
885.3650	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of mammals.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	. 555			
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999).  Bacillus thuringiensis Protein 11231 in Com Grain: A Dietary Toxicity Study with the Northern Bobwhite.  MSL-16161; an unpublished study conducted for Monsanto Company.	449043-15	Monsanto Com	pany	OWN	Dated August 19, 1999
154-17 885.4100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for avian inhalation exposure.					
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors.					
154-19 885.4200	L., M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Com Lines MON 853 and MON 859 as a Feed Ingredient for Catlish. MSL-16164; an unpublished study conducted for Monsanto Company.	449043-19	Monsanio Com	ipany	OWN .	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I		Date February 13, 2003	

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Date: February 13, 2003 Applicant's/Registrant's Name	& Address: 3th Street, N.W., Suite 660, Washington, D.C. 2000	5		EPA Reg. No./File Symbol: 524-L	
	ingiensis Cry3Bb1 and the genetic material (vector 2				<u>'                                      </u>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-20 885.4240	Drotter, K.R. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11098 in Corn Pollen: 48-flour Static Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna). MSL-15988; an unpublished study conducted for Monsanto Company.	449043-18	Monsonto Compa	oy OWN	Dated August 19, 1999
154-21 885.4280	Not applicable since corn is not grown in close proximity to estuarine or marine environments.				
154-22 885.4300	Not applicable since Cry3Bb1 is plant-incorporated and not 'applied' to crops.	·			
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringlensis Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (Hippudamia convergens). MSL-16166; an unpublished study conducted for Monsanto Company.	449043-14	Monsanto Compa	ıy OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999).  Lacillus thuringiensis Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate.  MSL-16162; an unpublished study conducted for Monsanio Company.	449043-16	Monsanto Compai	ıy <u>OWN</u>	Dated August 19, 1999
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Date: February 13, 2003				EPA Reg. N	No./File Symbol: 524-LEI	Page 9 of 16
	3th Street, N.W., Suite 660, Washington, D.C. 2000.				Corn Event MON 863	
Ingredient Bacillus thur.	ingiensis Cry3Bb1 and the genetic material (vector 2	ZMIR13L) necessa	ry for its production i	n event MO	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Com Tissue Containing the Bacillus thuringiensis Protein 11098 to Collembola (Folsomia candida). MSL-15988; an unpublished study conducted for Monsanto Company.	449043-17	Monsanto Com	pany	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with Green Lacewing Larvae (Chrysoperla carnea). MSL-16165; an unpublished study conducted for Monsanto Company.	449043-12	Молѕалю Сом	pany	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). Bacillus thuringiensis Protein 11231: A Dietary Study with the Parasitic Hymenoptera (Nasania vitripennis). MSL-16167; an unpublished study conducted for Monsanto Company.	449043-13	Monsanto Com	ралу	OWN	Dated August 19, 1999
154-23 885,4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Com Events on Nontarget Organisms: Preliminary Results. An unpublished report prepared by Monsanto Company.	453484-02	Monsento Com	рапу	own	Dated February 20, 2001
154-23 885.4340	Juan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Lietary Effects of Transgenic Bacillus thuringiensis (Bt) Com Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, Coleonegilla maculata, MSI-16936: an unpublished study conducted by Magest 10. Townson.	453613-01	Monsanto Com	pany	own	Dated March 20, 2001
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs		Date February 13, 2003	

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Date: February 13, 2003	0.1		·	EPA Reg. N	No./File Symbol: 524-LB	I Page 10 of I
	3th Street, N.W., Suite 660, Washington, D.C. 2000		<del></del>		Corn Event MON 863	
	ngiensis Cry3Bb1 and the genetic material (vector 2		ary for its production in	n event MO	N 863 corn	r
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, Hippodamia convergens. MSL-17171; an unpublished study conducted for Monsanto Company.	453613-02	Monsanto Com	рапу	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179; an unpublished study conducted by Monsanto Company.	455382-06	Monsanto Com	pany	OWN	Dated November 5, 200
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic Bacillus thuringiensis (Bt) Com Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, Coleomegilla maculata. MSL-16907; an unpublished study conducted by Maceonic Company	455382-04	Monsanto Com	pany	OWN	Dated November 5, 200
154-23 885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Com Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (Danus plexippus) via Laboratory Bioassay. MSL-17235; an ampublished study conducted for Monsanto Company.	455382-05	Monsanto Com	pany	OWN	Dated November 5, 200
154-23 885.4340	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein in vitro. C3NTO; an unpublished study conducted by Monsanto Company.	455382-07	Monsanto Com	рапу	OWN	Dated November 5, 200
Signatu/e			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N		Date February 13, 2003	

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Date: February 13, 2003				EPA Reg. No	o./File Symbol: 524-LEI	Page 11 of 16
Applicant's/Registrant's Name Monsanto Company, 600 1	3th Street, N.W., Suite 660, Washington, D.C. 2000.			Product: C	Corn Event MON 863	
Ingredient Bacillus thuri	ngiensis Cry3Bb1 and the genetic material (vector 2	ZMIR13L) necessa	ary for its production in	event MON	l 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614; an unpublished assessment prepared by Monsanto Company	455770-03	Monsanto Comj	рапу	own	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. An unpublished report prepared by Monsanto Company.	456530-03	Monsanto Comp	рапу	OWN	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials.  Report MSL 17531 - an unpublished curds conducted by a conduct		Monsanto Com	pany	own	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137, an unpublished study conducted for Monsanto Company.		Monsanto Com	pany	OWN	Dated September 10, 2002
1,54-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified Bucillus thuringiensis Protein 11231 on Honey Bee Larvae. MSL-16168; an unpublished study conducted for Monsanto Company.	449043-10	Monsanto Com	pany	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I		Date February 13, 2003	

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Date: February 13, 2003				EPA Reg. N	lo./File Symbol: 524-LEI	Page 12 of 16
Applicant's/Registrant's Name 8		_				
<del></del>	th Street, N.W., Suite 660, Washington, D.C. 2000				Corn Event MON 863	<del></del>
Ingredient Bacillus thurir	igiensis Cry3Bb1 and the genetic material (vector 2	ZMIR13L) necessa	ry for its production in	event MOI	N 863 corn	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	***************************************	Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified Bacillus thuringiensis Protein 11231 on Adult Honey Bees (Apis mellifera L.). MSL-16169; an unpublished study conducted for Monsanto Company.	449043-11	Monsanto Company		OWN	Dated August 19, 1999
154-26 885.4600						
	Not applicable; no triggers hit for tier III testing.					······································
154-28 885.4700			·			
	Not applicable; no triggers hit for tier III testing.		ļ	· · · · · · · · · · · · · · · · · · ·		
154-29 885.4750	Not applicable since com is not grown in an aqueous environment.					
885:5200	Martin, J.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the B.J. Protein 11098 as a Component of Insect Protected Corn. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Comp	any	OWN	Dated June 20, 2000
Signature	-	<del>adria (adriada a abril 1   1   1   1   1   1</del>	Name and Title Dennis P. Ward, Ph. Regulatory Affairs M		Date February 13, 2003	<del>P. (a. 1. desk<b>o</b>rt 1971 - 1. 1971 - 1</del> . <del>fer beste de deskorte</del>

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	me & Address: 0 13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 2000 uringiensis Cry3Bb1 and the genetic material (vector	<del></del>	Prod		Page 13 of 16
Guideline Reference Numb		MRID Number	Submitter	Status	Note
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Com Rootworm Protected Com Event MON 863. MSL-17102, an unpublished		Monsanto Company	OWN	Dated September 10. 2002
885.5300	Not applicable since corn is not grown in an aqueous environment.				
885.5400	Not applicable since corn is not grown in an aqueous environment.				
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bacillus thuringiansis Cry318 Protein, and the Genetic Material Necessary for its Production in Corn (Vectors 7418121 7418131 and 74418141).	450297-01	Monsanto Company	own_	Dated January 13, 2000
	Maughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product. An unpublished report prepared by Monsanto Company.	453484-01	Monsanto Company	OWN	Dated February 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 13, 2003	

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	D	ATA MATRIX				
Date:_February 13, 2003				EPA Reg. N	lo./File Symbol: 524-LE	Page 14 of 1
Applicant's/Registrant's Name & Address:  Monsanto Company, 600 13th Street, N.W., Suite 6	660, Washington, D.C. 2000	05		Product:	Corn Event MON 863	
Ingredient Bacillus thuringiensis Cry3Bb1 and	the genetic material (vector)	ZMIR13L) necessa	ry for its production in	n event MO	N 863 corn	
Guldeline Reference Number   Guldeline Study Name	·	MRID Number	Submitter		Status	Note
Agronomic Equivalency Hybrids as Determined in	rson and D.P. Ward (2001), of Corn Event MON 863 n Year 2000 Field Trials. An icted by Monsanto Company.	453484-03	Monsanto Com	рапу	OWN _	Dated February 20, 200
Corn Rootworm and Corn Treatments - Results of	ficacy of MON 863 Against nparison to Insecticide Year 2000 Field Trials. An icied by Monsanto Company.	453613-03	Monsanto Com	pany	OWN	Dated March 20, 2001
for Registration of Event	in Support of the Application MON 863: Corn Rootworm MIR13L); EPA File Symbol	454240-00	Monsanto Com	рапу	OWN	Dated May 21, 2001
for Registration of Event	in Support of the Application MON 863: Com Rootworm MIR13L); EPA File Symbol	455382-00	Monsanto Com	pany	OWN	Dated November 5, 2001
Vaughn, T.T., M. Picau. (2001). Comparing the E 863 to Three Corn Root Rootworn (Diabrotica b	R. Knutson and T. Coombe Efficacy of MON 853 and MON worm Species, Northern Corn arberi). Southern Corn unctata howardi), and Western			<u> </u>		Dated
Com Laste or a Ch wea	ilora visailara) NATO DDT 4- na	455382-08	Monsanto Com	рапу	OWN	November 5, 200
Signature			Name and Title Dennis P. Ward, Ph. Regulatory Affairs N		Date February 13, 2003	

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Date: February 13, 2003				EPA Reg. No./File Sy	ymbol: 524-LEI	Page 15 of 16
Applicant's/Registrant's Name &	Address:					
	3th Street, N.W., Suite 660, Washington, D.C. 2000.			Product: Corn Eve		
	igiensis Cry3Bb1 and the genetic material (vector 2		<del></del>	<del></del>		
Guideline Reference Number	Guideline Study Name	NRID Number	Submitter		Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556; an unpublished report prepared by Monsanto Company.	455770-01	Monsanto Com	sany	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766, an unpublished report prepared by Managaro Company.	456530-01	Monsanto Com	any	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Com Event MON 863. MSL-17782, an unpublished study conducted for Monsanto Company.	456530-02	Monsanto Com	oany	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal					
	Technology - Yield Rootworm, Report MSL-17993, an impublished analysis conducted for Monsanto Company.	456923-01	Monsanto Com	pany	OWN	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotransferase II as a Plant Pesticide Formulation Inert Ingredient. 93-132E	430547-00	Monsanto Com	pany	OWN	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph Regulatory Affairs I	Date D Februa	ary 13, 2003	

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Date: February 13, 2003			,	EPA Reg. N	lo./File Symbol: 524-LEI	Page 16 of 16
	3th Street, N.W., Suite 660, Washington, D.C. 2000			Product: (	Corn Event MON 863	
Ingredient Bacillus thuri	ingiensis Cry3Bb1 and the genetic material (vector	ZMIR13L) necessa	ry for its production in	n event MO	N 863 corn	· · · · · · · · · · · · · · · · · · ·
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	···········	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTH) in Albino Mice. ML-91-409, an unpublished study conducted by Monsanto Company	430547-01	Monsanto Com	pany	OWN	Dated November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>In vitro</i> Mammalian Digestion Models. IRC-91-ANA-06, an unpublished study conducted by Monsanto Company	430933-02	Monsanto Corn	рапу	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferuse II.	430547-02	. PL			Dated November 23, 1993
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Signature	<u> </u>		Name and Title Dennis P. Ward, Ph. Regulatory Affairs N		Date February 13, 2003	******************



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Date: February 13, 2003 Applicant's/Registrant's Name & Address:	···		EPA Reg. N	lo./File Symbol: 524-LE	Page 2 of 16
Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 2000				Orn Event MON 863	
Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material (vector 2				ŧ .	
Guideline Reference Number Guideline Study Name	MRID Number	Submitter		Status	Note
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Signature		Monsanto Comp Name and Title Dennis P. Ward, Ph. Regulatory Affairs N	D.	Date February 13, 2003	May 21, 2001

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#### 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX Date: February 13, 2003 Page 3 of 16 EPA Reg. No./File Symbol: 524-LEI Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005 Product: Corn Event MON 863 Bacillus thuringiensis Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn Ingredient Guldeline Reference Number Guideline Study Name MRID Number Status Note Submitter Dated OWN November 5, 2001 Monsanto Company Dated Monsanto Company OWN May 21, 2001 Dated Monsanto Company OWN April 7, 2001 Name and Title Signature Date Dennis P. Ward, Ph.D. February 13, 2003

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Date: February 13, 2003	·	·			EPA Reg. N	lo./File Symbol: 524-LE	I Page 4 of 16
Applicant's/Registrant's Name & Ad Monsanto Company, 600 13 <sup>th</sup> S Ingredient Bacillus thuringies				v for its production in		orn Event MON 863	
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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington			Corn Event MON 863	
Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic mate		for its production in event MO	N 863 corn	r
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Date: February 13, 2003	_				EPA Reg. N	lo./File Symbol: 524-LEI	Page 6 of 10
Applicant's/Registrant's Name 8	k Address:  th Street, N.W., Suite 660, Washi	ington D.C. 2000	)5			orn Event MON 863	<u> </u>
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Date: February 13, 2003					EPA Reg. N	o./File Symbol: 524-LEI	Page 7 of 16
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	iensis Cry3Bb1 and the gene	etic material (vector			_		
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Date: February 13, 2003		EPA Reg.	No./File Symbol: 524-LEI	Page 8 of 16
Applicant's/Registrant's Name & Address:  Monsanto Company, 600 13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20005  Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material (vector ZM)	IID13I ) necessary		Corn Event MON 863	
Guideline Reference Number   Guideline Study Name	MRID Number	Submitter	Status	Note
		Monsanto Company	OWN	Dated August 19, 1999
		Monsanto Company	OWN	Dated August 19, 1999
Signature		Monsanto Company Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	OWN Date February 13, 2003	Dated August 19, 1999

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Date: February 13, 2003			EPA Reg	No./File Symbol: 524-LE	Page 9 of 16
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	*** ***		Monsanto Company	OWN	March 20, 2001
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		1	Dennis P. Ward, Ph.D.	February 13, 2003	•
			Regulatory Affairs Mgr.		

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**SEPA** 

Form Approved OMB No. 2070-0060

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Washington, D.C. 20460

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	DATA MATRIX			
Date: February 13, 2003		EPA	Reg. No./File Symbol: 524-LE	I Page 10 of 16
Applicant's/Registrant's Name & Address:  Monsanto Company, 600 13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20			uct: Corn Event MON 863	
Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material (vecto	or ZMIR13L) necessar	ry for its production in event	MON 863 corn	<u> </u>
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		Monsanto Company	OWN	Dated March 20, 2001
		Monsanto Company	OWN	Dated November 5, 2001
		Monsanto Company	OWN	Dated November 5, 2001
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		Monsanto Company	OWN	Dated November 5, 2001
		Monsanto Company	OWN	Dated November 5, 2001
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Washington, D.C. 20460

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401 M Street, S.W., Washington, DC 20460. Do not send the form to this add	DATA MATRIX	· - · - · · · · · · · · · · · · · · · ·		
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		Monsanto Company	OWN	Dated January 8, 2002
		Monsanto Company	OWN	Dated April 8, 2002
		Monsanto Company	OWN	Dated September 10, 2002
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		Monsanto Company	OWN	August 19, 1999
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401 M Street, S.W.

Washington, D.C. 20460

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#### DATA MATRIX Date: February 13, 2003 EPA Reg. No./File Symbol: 524-LEI Page 12 of 16 Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005 Product: Corn Event MON 863 Bacillus thuringiensis Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn Ingredient Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Dated August 19, 1999 Monsanto Company Dated Monsanto Company June 20, 2002 Name and Title Signature Date February 13, 2003 Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.

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Date: February 13, 2003			•	EPA Reg. No	p./File Symbol: 524-LEI	Page 13 of 16
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Date: February 13, 2003		EPA R	eg. No./File Symbol: 524-LEI	Page 16 of 16
Applicant's/Registrant's Name & Address:  Monsanto Company, 600 13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20005	<u></u>		t: Corn Event MON 863	·-··-
Ingredient Bacillus thuringiensis Cry3Bb1 and the genetic material (vector ZMIR)	L) necessary	for its production in event M	MON 863 corn	
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		Monsanto Company	OWN	Dated November 23, 1993
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			PL	Dated November 23, 1993
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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**Public File Copy** 

# CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

# CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

182

Monsanto Company

00-CR-032E-17

Page 38 of 49

# **PRODUCT LABEL**

Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn' are attached. This label supersedes the label previously submitted to EPA, dated February 11, 2003.

# Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: YieldGard Rootworm<sup>TM</sup>: Rootworm Protection]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

# **Active Ingredient:**

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (ZMIR13L) in event MON 863 com......................0.001 - 0.006%

# Other Ingredients:

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

## **CAUTION**

TM YieldGard Rootworm is a trademark of Monsanto Technology LLC

EPA Registration No. 524-LEI

EPA Establishment No. 524-MO-002

©2003 Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with this labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

# **Insect Resistance Management**

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Corn Event MON 863 corn.

Refuge planting options include: blocks, strips or border rows. Refuge acres must be planted within or adjacent to the Corn Event MON 863 field. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If row strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted. If border rows are implemented they should be surrounding the Corn Event MON 863 field.

External refuges must be planted in fields adjacent to the Corn Event MON 863 fields.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

# Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the B.t. protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western com rootworm (Diabrotica virgifera virgifera) Northern com rootworm (Diabrotica barberi) Mexican com rootworm (Diabrotica virgifera zeae)



# CONFIDENTIAL ATTACHMENT





Amendment of the Application to Register a Bacillus thuringiensis
Cry3Bb1 Protein and the Genetic Material Necessary for its
Production (Vector ZMIR13L) in Event MON 863 Corn;
EPA File Symbol 524-LEI

# CONFIDENTIAL ATTACHMENT

# **AUTHOR**

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

# DATE

February 13, 2003

# SUBMITTING REGISTRANT

Monsanto Company 600 13<sup>th</sup> Street N.W. Suite 660 Washington, DC 20005

# MONSANTO REFERENCE No.

00-CR-032E-17



# CONFIDENTIAL BUSINESS INFORMATION

**CBI Cross Reference Number 1** 

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

Pages Reason for Deletion		FIFRA Reference
37 <b>&amp;</b> 38	Discloses commercial information	§10(d)(1)(A), (B) or (C)



Raintation 524-528
Volume 4 of 4

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Page is not included in this copy.
Pages $\frac{189}{100}$ through $\frac{190}{100}$ are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product inert impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

-



Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
http://www.monsanto.com

February 13, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Interim IRM plan for corn event MON 863

Response to your request of February 12, 2003

Dear Mr. Hutton:

Pursuant to your request for additional product durability simulations with the Caprio model, we are providing the results of simulations with lower survival rates for susceptible rootworms. These durability simulations supplement those provided to the Agency in a letter to Dr. Andersen, dated December 13, 2002.

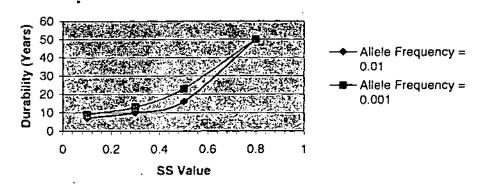
For this set of durability simulations, we have set the degree of dominance for a resistant allele at 0.8 (a very conservative value) and have run the model with a 20% non-Cry3Bb1 refuge. Durability estimates are computed as a function of resistant rootworm survival and resistance allele frequency. The results over a range of values are presented in Table 1 and graphically presented in Figure 1.

**Table 1.** Caprio model simulations for corn rootworm rate of resistance to Cry3Bb1 protein produced in corn event MON 863 computed as a function of susceptible insect survival and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.

<del>,</del>	Years to Resistance Development			
Survival (%)	Allele Frequency = 0.01	Allele Frequency = 0.001		
10	7 years	9 years		
30	10 years	13 years		
50	16 years	23 years		
80	>50 years	>50 years		

Figure 1. Graphic representation of Caprio model predictions for product durability as a function of susceptible rootworm survival (SS) and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.

# Durability as a function of SS Survival



As indicated in our December 13th letter to Dr. Andersen, the results from three years of field efficacy trials with corn event MON 863, from which more than 7,500 plants were rated for root damage, indicate that resistance allele frequency is actually lower than the conservative value of 0.01. Furthermore, the results of these trials indicate that average susceptible insect survival is 50%. Under a scenario where the resistance allele is assumed to be partially dominant (i.e. 0.8), occurring at a frequency of 0.01, and susceptible insect survival is 50%, then an extremely conservative estimate of product durability would be 16 years with a 20% refuge. A more reasonable prediction of product durability, where resistance allele frequency is 0.001, would be 23 years with a 20% refuge.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto Ty Vaughn, Monsanto



# **FACSIMILE TRANSMISSION**

MONSANTO COMPANY
MAIL ZONE BB3N
700 CHESTERFIELD PARKWAY W.
ST. LOUIS, MO 63017 USA

February 12, 2003

TO

Robyn Rose

EPA / OPP / BPPD

FAX #

703-308-7026

FROM

Dennis P. Ward, Ph.D.

Regulatory Affairs Manager

Telephone:

1-636-737-6631

Telefax:

1-636-737-5943

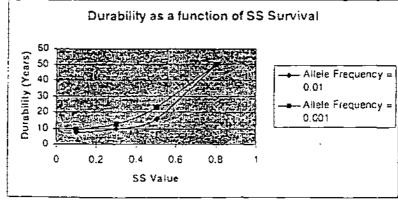
email:

dennis.p.ward@monsanto.com

# NUMBER OF PAGES (including cover): 1

MESSAGE: Robyn – The predictions for product durability based on a dominance value of 0.8 with a 20% refuge, modeled as a function of SS survivability and initial allele frequency are shown below. I'll put this in a formal submission to Phil.

SS_Value	e  Allele Frequency = 0.01	Allele Frequency = 0.001
0.1_	7 years	9 years
0.3	10 years	13 years
0.5	16 years	23 years
0.8	>50 years	l>50 years



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Phil, per your request, here is the output from the Caprio model using various SS values. Please let me or Russ know if you need anything else. Sheila Schuette

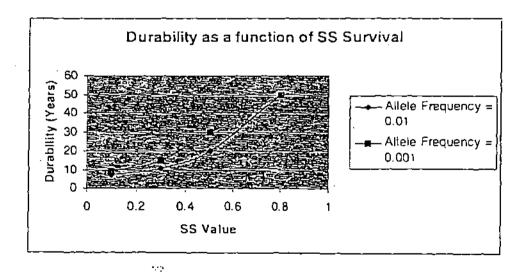
Here is the first run at this and the parameters used. We have good evidence that 0.5 is a realistic value for survival on average. In the most extreme cases, we have seen about 0.17 and as high as 0.95. The dominance value was held at 0.7 and refuge at 20%.

Here are the output values for 20% refuge, heterozygote value of 0.7 (an intermediate level of dominance) and an initial allele frequency of 0.001

SS	Durability
Value	
0.1	9
0.3	15
0.5	30
0.8	>100

Here are the values when the refuge is 20%, heterozygote frequency is 0.7 and an initial allele frequency is 0.01.

SS	Durability
Value	
0.1	7
0.3	11
0.5	20
0.8	>100



15/1





# **FACSIMILE TRANSMISSION**

MONSANTO COMPANY
MAIL ZONE BB3N
700 CHESTERFIELD PARKWAY W.
ST. LOUIS, MO 63017 USA

February 13, 2003

TO

Mike Mendelsohn

EPA / OPP / BPPD

FAX#

703-308-7026

FROM :

Dennis P. Ward, Ph.D.

Regulatory Affairs Manager

Telephone:

1-636-737-6631

Telefax:

1-636-737-5943

email:

dennis.p.ward@monsanto.com

NUMBER OF PAGES (including cover): 3

**MESSAGE**: Mike – Would you please pass copies of the attached letter on to both Phil and Robyn? Thanks.

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aron dan raio

Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 MONSANTO COMPANY
700 CHESTERFIELD PXWY NORTH
CHESTERFIELD, MISSOURI Ó3198
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February 13, 2003

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Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Interim IRM plan for corn event MON 863

Response to your request of February 12, 2003

Dear Mr. Hutton:

Pursuant to your request for additional product durability simulations with the Caprio model, we are providing the results of simulations with lower survival rates for susceptible rootworms. These durability simulations supplement those provided to the Agency in a letter to Dr. Andersen, dated December 13, 2002.

For this set of durability simulations, we have set the degree of dominance for a resistant allele at 0.8 (a very conservative value) and have run the model with a 20% non-Cry3Bb1 refuge. Durability estimates are computed as a function of resistant rootworm survival and resistance allele frequency. The results over a range of values are presented in Table 1 and graphically presented in Figure 1.

Table 1. Caprio model simulations for corn rootworm rate of resistance to Cry3Bb1 protein produced in corn event MON 863 computed as a function of susceptible insect survival and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.

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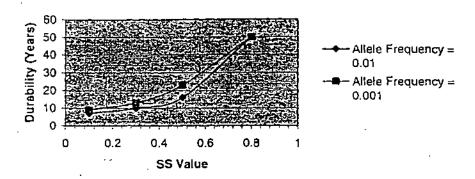
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Mr. P. Hutton 02/13/2003 Page -2-

Figure 1. Graphic representation of Caprio model predictions for product durability as a function of susceptible rootworm survival (S5) and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.

# Durability as a function of SS Survival



As indicated in our December 13<sup>th</sup> letter to Dr. Andersen, the results from three years of field efficacy trials with corn event MON 863, from which more than 7,500 plants were rated for root damage, indicate that resistance allele frequency is actually lower than the conservative value of 0.01. Furthermore, the results of these trials indicate that average susceptible insect survival is 50%. Under a scenario where the resistance allele is assumed to be partially dominant (i.e. 0.8), occurring at a frequency of 0.01, and susceptible insect survival is 50%, then an extremely conservative estimate of product durability would be 16 years with a 20% refuge. A more reasonable prediction of product durability, where resistance allele frequency is 0.001, would be 23 years with a 20% refuge.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto Ty Vaughn, Monsanto

00-CR-032E-18

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Robyn Rose

02/19/03 03:43 PM

To: Robyn Rose

cc: cc:

Subject: Rootworm Bt corn

..... Forwarded by Phil Hutton/DC/USEPA/US on 02/07/03 12:51 PM .....



Fred Gould <a href="fred\_gould@ncsu.ed">fred\_gould@ncsu.ed</a>

To: Sharlene Matten/DC/USEPA/US@EPA,

rose.robin@epamail.epa.gov, Phil Hutton/DC/USEPA/US@EPA

cc:

02/06/03 04:25 PM

Subject: Rootworm Bt corn

Phii.

I contacted Sharlene about the Monsanto written response to the EPA SAP and she said that I should contact you.

Monsanto indicates that the SAP concerns about initial resistance gene frequencies, and about quantitative genetic resistance are unwarranted based on theory and based on experiments that have been

performed.

The science in the Monsanto response is lacking. First of all they do not take into account the fact that alleles for quantitative genetic resistance are expected, based on theory and past experiments to be at higher frequencies

than major resistance genes. The only times when resistance due to major genes and to quantitative genetic variation is expected to

develop at the same rate is when gene frequencies are comparable. When there is a high degree of quantitative genetic variation

resistance can evolve MUCH faster.

Monsanto indicates that the experiments they describe prove that resistance allele frequencies are low. This is not true. Those experiments would

only have picked up major non-recessive genes for resistance. They could not detect anything about minor genes.

Monsanto only looks at selection pressure that could be inferred from larval mortality. As written in the 2002 EPA SAP document, that is likely to be

an underestimate of the selection pressure, so it would underestimate the rate of resistance development.

Monsanto never addresses the issue of once you start with a 20% refuge it will be impossible to go back to a substantially larger refuge, for social reasons.

I feel like Monsanto keeps avoiding the fact that the previous EPA SAPs (1998, 2001) specifically stated that the BT cultivars had to be High Dose.

Monsanto has not provided scientific justification for a moderate dose approach.

If you need more details, please let me know.

Fred

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Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631

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February 11, 2003

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Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863

EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing a revised label and Confidential Statement of Formula for Corn Event MON 863.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the Confidential Attachment and subject to the provisions of FIFRA Section 10(g), Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

oincerely,

Dennis P. Ward, Ph.D.

Regulatory Affairs Manager

Mr. P. Hutton 2/11/2003 Page 2 of 15

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto

Please read instructions	on reverse before completing	form.	Form A	pproved. OM	B No. 2070	3-0060. Approvat E	Expires 2-28-95
<b>≎</b> EPA	Environment	United States tal Protectington, DC 2	tion Agend	гу		Registration  Amendment  Other	OPP Identifier Number
	Applicat	ion for P	esticide - :	Section I			
Company/Product Number     File 5	Symbol 524-LEI		2. EPA Produc		utton	3. Propos	sed Classification
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Russell P.	Schneider	Title	Regulatory A	Affairs Direc	ctor	+ '	33-2866
	I have made on Jhis form and wingly false or misleading state	all attachment				‡ † <b>†</b>	6. Date Application Received (Stamped)
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4. Typed Name Dennis P. Ward	Tel. (636) 737-6631	5. Oate	February 11				301
EPA Form 8570-1 (Rev	. 3-94) Previous editions are	obsolete.	White - EP	A File Copy (	(orīginal)	Yellow - Applic	ant Copy

# CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

202

Page 4 of 15

# PRODUCT LABEL

The subject of this submission is a request for registration of *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material (ZMIR13L) necessary for its production in all corn lines and varieties containing event MON 863. A full and unrestricted FIFRA section 3 registration is being sought to support commercialization of this product. Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn Seed' are attached. This label supersedes the label previously submitted to EPA on February 4, 2003.

The proposed label is for the pesticidal protein, Cry3Bb1, contained within event MON 863 corn seed.

# Plant-Incorporated Protectant Label

# Corn Event MON 863: Rootworm Protected Corn Seed

[Alternate brand name: YieldGard® Rootworm: Rootworm Protection]

This package contains corn rootworm-protected corn seed producing Cry3Bb1, an insecticidal protein from *Bacillus thuringiensis* (B.t.). This protein is effective in controlling damage caused by corn rootworm (*Diabrotica* spp.) larval feeding on corn roots.

# Active Ingredient:

Corn-produced B.t. Cry3Bb1 protein and the genetic material (vector ZMIR13L) necessary for its production in corn event MON 863..................0.0096%

# Other Ingredients:

Substance produced by a marker gene and the genetic material (vector ZMIR13L) necessary for its production in corn event MON 863......<0.00001%

Percentage (wt/wt) on a dry weight basis.

# KEEP OUT OF REACH OF CHILDREN CAUTION

® YieldGard is a trademark of Monsanto Technology LLC.

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017

NET CONTENTS

### Corn Event MON 863: Rootworm Protected Corn Seed

# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

# Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the B.t. protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (Diabrotica virgifera virgifera)
Northern corn rootworm (Diabrotica barberi)
Mexican corn rootworm (Diabrotica virgifera zeae)

# Insect Resistance Management

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Corn Event MON 863 corn.

Refuge planting options include: blocks, strips or border rows. Refuge acres must be planted within or adjacent to the Corn Event MON 863 field. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If row strips within a corn field are implemented, then at least 4, and preferably 12 consecutive rows should be planted. If border rows are implemented they should be surrounding the Corn Event MON 863 field.

External refuges must be planted in fields adjacent to the Corn Event MON 863 fields.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticide treatments, including seed treatments or granular insecticides, to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

Page 7 of 15



Amendment of the Application to Register a *Bacillus*thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector
ZMIR13L) Necessary for its Production in Corn Event MON 863;
EPA File Symbol 524-LEI

# CONFIDENTIAL ATTACHMENT

#### **AUTHOR**

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

#### SUBMISSION DATE

February 11, 2003

#### SUBMITTING REGISTRANT

Monsanto Company 600 13<sup>th</sup> Street N.W. Suite 660 Washington, DC 20005

# MONSANTO REFERENCE No.

00-CR-032E-16

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Page 1 of 3

# CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

Page	Reason for Deletion	FIFRA Reference
4	Discloses commercial information	§10(d)(1)(A), (B) or (C)

Volume 4 of 4	
Page 200 is not included in this copy.	
Pages through are not included in this copy.	
The material not included contains the following type of information:	-
Identity of product inert ingredients.	
Identity of product inert impurities.	
Description of the product manufacturing process.	
Description of quality control procedures.	
Identity of the source of product ingredients.	
Sales or other commercial/financial information.	
A draft product label.	
The product confidential statement of formula.	
Information about a pending registration action.	
FIFRA registration data.	
The document is a duplicate of page(s)	
The document is not responsive to the request.	



Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631

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Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863

EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing an updated Data Matrix for Monsanto's application to register Corn Event MON 863. This updated matrix indicates which of the data requirements for microbial pesticides (40 CFR §158.740) have been satisfied or are not applicable to Cry3Bb1.

Monsanto is also providing revised labeling for Corn Event MON 863 as part of this amendment. Lastly, we are notifying the Agency of the alternate brand name, YieldGard Rootworm: Rootworm Protection.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)

Subject to the provisions of FIFRA Section 10(g), Monsanto does not object to placement of materials contained in this submission in the Public Docket.

90°1

Mr. P. Hutton 2/4/2003 Page 2 of 45

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD

Russell Schneider, Monsanto



Dennis P. Ward, Ph.D. Regulatory Affairs Manager (636) 737-6631 Monsanto Company 700 Chesterfield Pkwy West Chesterfield, MO 63017 PHONE (314) 694-1000 FAX (636) 737-5943 http://www.monsanto.com

February 4, 2003

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Monsanto is also providing revised labeling for Corn Event MON 863 as part of this amendment. Lastly, we are notifying the Agency of the alternate brand name, YieldGard Rootworm: Rootworm Protection.

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Mr. P. Hutton 2/4/2003 Page 2 of 45

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Sincerelya

Dennis P. Ward, Ph.D. Regulatory Affairs Manager

Att: Administrative materials.

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto

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# CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

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# NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharamacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Meantation 524-528
Volume 4 of 4
Page is not included in this copy.
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